(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
12 July 2001 (12.07.2001)

PCT

(10) International Publication Number
WO 01/49245 A2

(51) International Patent Classification[7]: A61K

(21) International Application Number: PCT/SE01/00228

(22) International Filing Date: 7 February 2001 (07.02.2001)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
09/502,074 10 February 2000 (10.02.2000) US

(71) Applicant *(for all designated States except US)*: **IT-MEDICAL AG** [CH/CH]; Zugerstrasse 74, CH-6341 Baar (CH).

(72) Inventor; and

(75) Inventor/Applicant *(for US only)*: **FORSELL, Peter** [SE/CH]; Kirchgasse 4, CH-6313 Menzingen (CH).

(74) Agents: **HAGSTRÖM, Leif** et al.; Bergenstråhle & Lindvall AB, P.O. Box 17704, S-118 93 Stockholm (SE).

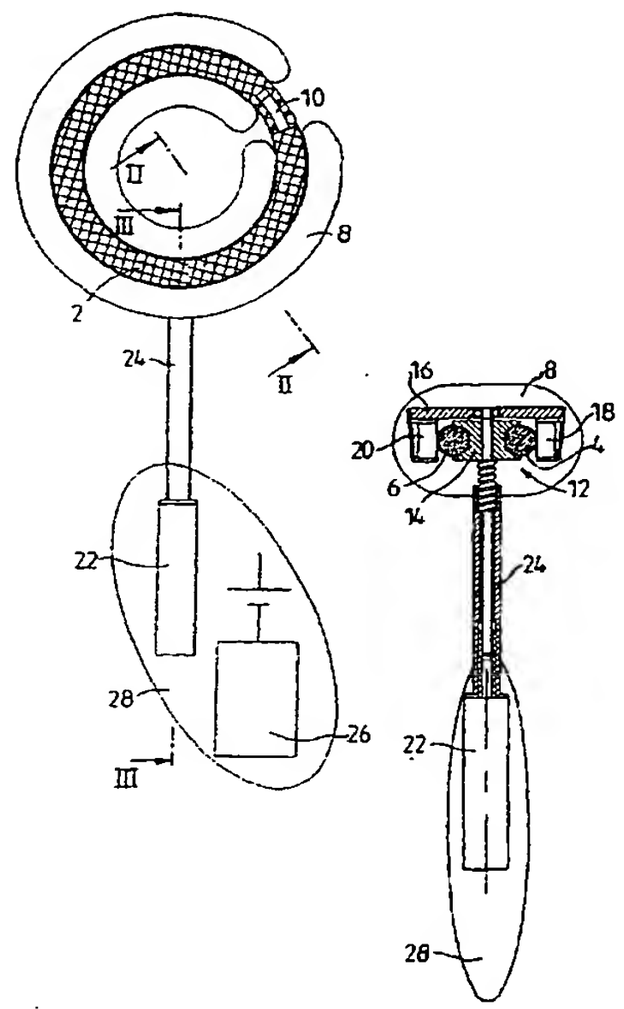
(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published:
— *Upon request of the applicant, before the expiration of the time limit referred to in Article 21(2)(a).*
— *Without international search report and to be republished upon receipt of that report.*
— *Without classification; title and abstract not checked by the International Searching Authority.*

[Continued on next page]

(54) Title: MECHANICAL HEARTBURN AND REFLUX DISEASE TREATMENT APPARATUS



(57) Abstract: A heartburn and reflux disease treatment apparatus for surgical application in the abdomen of a patient comprises an adjustable restriction device (2) adapted to engage the stomach close to the cardia or esophagus to form a restricted food passageway in the stomach or esophagus of the patient. A post-operation adjustment device (12) is designed to mechanically adjust the restriction device, preferably in a non-invasive manner, to enlarge or restrict the food passageway. The treatment apparatus allows post-operation daily adjustments of the restriction device to enlarge the food passageway when the patient eats and to restrict or close the food passageway between meals.

WO 01/49245 A2

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

SDOCID: <WO___0149245A2_I_>

MECHANICAL HEARTBURN AND REFLUX DISEASE TREATMENT APPARATUS

The present invention relates to a heartburn and reflux disease treatment apparatus, comprising an adjustable restriction device adapted to engage the stomach close to the cardia or esophagus of a patient to form a restricted food passageway in the stomach or esophagus of the patient. The term "patient" includes an animal or a human being.

Chronic heartburn and reflux disease is a widespread medical problem. This is often due to hiatal hernia, *i.e.* a portion of the stomach immediately below the gastric fundus slides upwardly through the esophageal hiatus. In consequence, stomach acids and foods are regurgitated into the esophagus.

In the late 1970s a prior art prosthesis called Angelchik, according to U.S. Patent No. 3875928, was used to operatively treat heartburn and reflux disease. However, the Angelchik prosthesis had a major disadvantage in that it was not possible to adjust the size of the restriction opening after the operation. A further disadvantage was that the prosthesis did not satisfactorily protect the esophagus and the surrounding area against injuries due to poor shape of the prosthesis. Therefore, operations using the Angelchik prosthesis are no longer practised.

An operation technique, semi-fundoduplicatio, is currently in use for treating heartburn and reflux disease. A most common operation is Nissen semi-fundoduplicatio, in which one takes the fundus of the stomach and makes a three-quarter of a turn around the esophagus and suture between the stomach and esophagus. Although this operation works fairly well it has three main disadvantages. Firstly, most patients treated in accordance to "ad modum Nissen" lose their ability to

belch. Secondly, many of these patients get dysphasia, *i.e.* have difficulties in swallowing after the operation. Thirdly, it is not possible to adjust the food passageway in the esophagus or stomach in any way after the operation. Characteristic for these patients is the variation of their problems over the course of a day. For example, many patients have difficulties during the night when they lie down because of stomach acid leaking up into the esophagus.

The object of the present invention is to provide a new heartburn and reflux disease treatment apparatus that eliminates the above noted problems of the known technique for treating heartburn and reflux disease.

This object is obtained by a heartburn and reflux disease treatment apparatus of the kind stated initially characterised by a post-operation adjustment device designed to mechanically adjust the restriction device to enlarge or restrict the food passageway, when the restriction device is implanted in the patient. As a result, the restriction device can be individually adjusted one or a few times after the operation so that a suitable restriction of the food passageway is obtained for every patient. Thus, the final restriction calibrated in this manner will reduce or completely eliminate the risk of stomach acids or foods regurgitating into the esophagus while the patient still is able to eat. Of course, in accordance with prior art the restriction device may suitably be provided with an inner cushion member that is deformable to permit normal enlargement of the food passageway during swallowing.

The adjustment device may be incorporated in the restriction device as well as being controlled by hydraulic means. The expression "post-operation" means that the adjustment device is capable of adjusting the restriction device after the operation without the need for invasive

ISDOCID: <WO___0149245A2_I_>

measures, such as penetration of the skin for example by injection needles or surgery, or by any other means that penetrate the skin. Though an injection port could be used in embodiments using hydraulic means, the port preferably would be for enabling a single, once-and-for-all, calibration of the amount of hydraulic fluid contained by the hydraulic means.

As an alternative to one or a few initial adjustments of the restriction device, the restriction device may advantageously be adjusted by the adjustment device to enlarge the food passageway when the patient eats and to restrict or close the food passageway between meals. In this case, the adjustment device preferably is operable in a non-invasive manner to adjust the restriction device. As a result, the restriction device performs like an artificial sphincter, which can be adjusted by the patient in connection with every food intake during the day, or possibly only in the morning to open up the food passageway and in the evening to close the food passageway.

The adjustment device may be adapted to adjust the restriction device in a non-manual manner.

The restriction device preferably is adapted to control, suitably steplessly, the cross-sectional area of the food passageway, *i.e.* to open and close the food passageway.

Generally the implanted restriction device comprises a holding device to prevent the region of the cardia to pass through the esophagal hiatus diaphragmatic. This could be achieved by an enlarged area that should pass the hole in the diaphragmatic muscle where the esophagus passes (a triangular opening surrounded by the crus muscles) or by fixing or holding the region of the cardia in place. The holding device may take the shape of a support member that provides a support for the restriction device upwardly against the diaphragm muscle or sutures or anything formed by human tissue.

Alternatively, the restriction device itself could prevent the region of the cardia from sliding up. Means for narrowing the triangular opening could also be provided.

In all applicable embodiments, the restriction device may take any shape and be either hydraulic or non-inflatable. Suitably, the support member is soft.

Preferably, the restriction device comprises an elongated, suitably non-inflatable, restriction member and forming means for forming the restriction member into at least a substantially closed loop around the esophagus or stomach, wherein the loop defines a restriction opening, whereby the adjustment device adjusts the restriction member in the loop to change the size of the restriction opening.

In the various embodiments hereinafter described the restriction member generally forms an at least substantially closed loop. However, the restriction member may take a variety of different shapes, such as the shape of a square, rectangle or ellipse. The restriction member in the substantially closed loop could for example be totally flat, like a belt. The shape of the restriction member may also be changed during use, by rotation or movement in any direction. A physical lumen, such as the passageway in the esophagus, is often easier to restrict by contracting at least two opposite or different sidewalls of the lumen against each other. Thus, the restriction member may be designed to perform such a contracting effect of the opposite walls of the esophagus. Either mechanical or hydraulic solutions may be employed to operate the restriction member. Alternatively, the restriction member may comprise an adjustable cuff, a clamp or a roller for bending the esophagus to close or almost close its passageway. Such a cuff, clamp or roller may also be utilised for squeezing the esophagus against human material inside the

body of the patient or against implanted structures of the treatment apparatus.

In accordance with a preferred first adjustment principle, the adjustment device is adapted to adjust the longitudinal extension of the elongated restriction member in a loop form.

In a preferred embodiment of the invention utilising the first adjustment principle, the restriction member comprises a main portion and two elongated end portions, and the adjustment device is adapted to establish longitudinal relative displacement between the end portions of the restriction member, so that the size of the restriction opening is adjusted. The forming means may comprise any suitable known or conventional device capable of practising the desired function, such as a spring material forming the elongated restriction member into the loop, so that the restriction opening has a predetermined size, and the adjustment device may adjust the restriction member against the spring action of the spring material. In other words, the restriction member may comprise a spring clip. The spring material may be integrated in the restriction member.

Preferably, the adjustment device comprises a movement transferring member, suitably a drive wheel, in engagement with at least one of the end portions of the restriction member and operable to displace one end portion relative to the other end portion of the restriction member. The drive wheel may advantageously be in engagement with both of the end portions of the restriction member and be operable to displace said end portions relative to each other. An elongated flexible drive shaft may be operatively connected to the drive wheel, for transferring manual or motor generated power from a location remote from the restriction member. In its simplest embodiment, the drive wheel may comprise a pulley in

frictional engagement with the restriction member. As an alternative, a gear rack may be formed on at least one of the end portions of the restriction member and the drive wheel may comprise a gear wheel in mesh with the gear rack. Other suitable known or conventional mechanisms may also or alternatively be used as the adjustment device.

The movement transferring member may alternatively comprise at least one cylinder and a piston, which is movable therein and is connected to one of the end portions of the restriction member, wherein the piston is operable to longitudinally displace one end portion of the restriction member relative to the other end portion of the restriction member. Alternatively, the movement transferring means may comprise two interconnected cylinders and two pistons in the respective cylinders connected to the end portions, respectively, of the restriction member, wherein the pistons are operable to longitudinally displace the end portions of the restriction member relative to each other. Other known or conventional devices also or alternatively can be used as the movement transferring member.

A motor, which is fixed relative to the main portion of the restriction member and has a rotating drive shaft operatively connected to the movement transferring member, may be positioned relative to the elongated restriction member such that the drive shaft extends transverse thereto. Alternatively, the motor may be positioned relative to the elongated restriction member such that the drive shaft extends substantially tangentially to the loop of the restriction member.

In another embodiment of the invention utilising the first adjustment principle, the elongated restriction member is longitudinally resilient and the adjustment device comprises a contraction device for longitudinally contracting

the resilient restriction member. Preferably, the elongated restriction member comprises a substantially non-resilient or rigid main portion and an end portion forming an elongated helical spring, which is contractible by the contraction device. The contraction device may suitably comprise an elongated flexible pulling member connected to the main portion of the restriction member and extending through the helical spring to contract the helical spring against an arresting member, which is fixed relative to the main portion of the restriction member. The pulling member may extend in an elongated tube joined at one end thereof to the arresting member, so that a motor remote from the restriction member may be attached to the other end of the elongated tube and pulls the pulling member through the tube to contract the helical spring.

In yet another embodiment of the invention utilising the first adjustment principle, the elongated restriction member comprises an elongated helical spring having a free end, and a body to which the spring is non-rotatably secured at its opposite end. The adjustment device is adapted to rotate the helical spring in one direction to enlarge the coils of the helical spring to longitudinally contract the spring and to rotate the spring in the opposite direction to reduce the size of the coils of the spring to longitudinally extend spring. As a preferred alternative, the restriction member comprises a further elongated helical spring having a free end and non-rotatably secured to the body at its opposite end, and the adjustment device comprises a drive shaft having two opposite end portions connected to the springs, respectively, at their free ends, the helical coils forming left and right hand helices, respectively. The adjustment device may alternatively comprise a gearing having an input shaft and two opposite aligned output shafts connected to the helical springs,

respectively, at their free ends, the input shaft being connected to said output shafts so that the output shafts rotate in the opposite directions upon rotation of the input shaft, the helical coils forming the same helices.

In accordance with a second adjustment principle, the adjustment device mechanically adjusts the restriction member so that at least a portion of a radially innermost circumferential confinement surface formed by the restriction member is substantially radially displaced.

In one embodiment of the invention utilising the second adjustment principle, the restriction member comprises an elongated voltage responsive element forming part of the confinement surface and capable of bending into a bow in response to a voltage applied across the element, wherein the radius of curvature of the bow is adjustable by changing the level of the voltage.

In another embodiment of the invention utilising the second adjustment principle, the adjustment device changes the diameter of an elastic annular element of the restriction member, which forms the confinement surface. Preferably, the forming means comprises a substantially rigid outer annular element coaxially surrounding the elastic annular element, and the adjustment device comprises means for pulling the elastic annular element radially outwardly towards the outer annular element to expand the elastic annular element. For example, the pulling means may comprise a plurality of threads secured to the elastic annular element along the circumference thereof and running from the elastic annular element via guide members attached to the outer annular element.

In yet another embodiment of the invention utilising the second adjustment principle, the forming means comprises a substantially rigid outer annular element, and the restriction member comprises an elongated helical spring extending

internally along the outer annular element and contacting the latter. The helical spring forms part of the circumferential confinement surface and has a free end. The restriction member further comprises a body to which the spring is non-rotatably secured at its opposite end. The adjustment device is adapted to rotate the helical spring in one direction to enlarge the coils of the spring to contract the circumferential confinement surface and to rotate the spring in the opposite direction to reduce the size of the coils of the spring to expand the circumferential confinement surface. As an alternative, which is preferred, the restriction member comprises two elongated helical springs forming part of the circumferential confinement surface and connected to the body of the restriction member. The adjustment device is adapted to rotate each spring in one direction to enlarge the coils of the spring to contract the circumferential confinement surface and to rotate the spring in the opposite direction to reduce the size of the coils of the spring to expand the circumferential confinement surface.

In accordance with a third adjustment principle, the restriction member comprises at least two separate elements, at least one of which is pivoted so that it may turn in a plane in which the restriction member extends, and the adjustment device is adapted to turn the pivoted element to change the size of the restriction opening. Preferably, the restriction member comprises a plurality of separate pivoted elements disposed in series, wherein each pivoted element is swinging in the plane, and the adjustment device is adapted to turn all of the pivoted elements to change the size of the restriction opening. For example, the pivoted elements may comprise lamellae arranged like the conventional adjustable aperture mechanism of a camera.

In accordance with a fourth adjustment principle, the adjustment device is adapted to fold at least two foldable frame elements of the restriction member towards each other. Preferably, the foldable frame elements comprise two substantially or partly semi-circular frame elements which are hinged together so that the semi-circular elements are swingable relative to each other from a fully open state in which they form part of a circle to a fully folded state in which they form part of a semi-circle. The same principle may be used with the swinging parts mounted together in one end and not in the other end.

Alternatively, the restriction device may comprise at least one, preferably two rigid articulated clamping elements positioned on opposite sides of the esophagus or stomach. The adjustment device is adapted to turn the clamping elements toward each other to clamp the esophagus or stomach between the clamping elements, thereby decreasing said area, and to turn the clamping elements away from each other to release the elements from the esophagus or stomach, thereby increasing said area.

In accordance with a fifth adjustment principle, the adjustment device is adapted to turn the restriction member around a longitudinal extension thereof, wherein the elongated restriction member is elastic and varies in thickness as seen in a cross-section thereof. Suitably, the elongated restriction member comprises an elastic belt.

In accordance with a sixth adjustment principle, the adjustment device is adapted to change the size of the restriction opening such that the outer circumferential confinement surface of the restriction member is changed.

In accordance with a seventh adjustment principle, the adjustment device is adapted to change the size of the

restriction opening such that the outer circumferential confinement surface of the restriction member is unchanged.

In accordance with an eighth adjustment principle, the elongated restriction member is flexible, and the adjustment device is adapted to pull a first portion of the flexible restriction member from a second portion of the flexible restriction member opposite the first portion in the loop to squeeze the esophagus or stomach between two opposite lengths of the elongated flexible restriction member to decrease the cross-sectional area in the esophagus or stomach and releases the esophagus or stomach from the flexible restriction member to increase the cross-sectional area.

In accordance with a ninth adjustment principle, the restriction device comprises at least two elements on different sides of the esophagus or stomach, and the adjustment device is adapted to squeeze the esophagus or stomach between the elements to decrease the cross-sectional area in the esophagus or stomach and to release the esophagus or stomach from the elements to increase the cross-sectional area. In all applicable embodiments, the restriction device may take any shape and be either hydraulic or non-inflatable. In members positioned on opposite or different sides of the esophagus or stomach and spaced apart along the food passageway in the esophagus or stomach, wherein the adjustment device is adapted to move the displacement members towards the esophagus or stomach to bend the latter, thereby reducing said area, and away from the esophagus or stomach to release them from the displacement members, thereby increasing said area. Suitably, the displacement members comprise rollers. The restriction device may also rotate a portion of the esophagus or stomach. The bending or rotating members may take any shape and be either hydraulic or non-inflatable.

;DOCID: <WO___0149245A2_I_>

The restriction device may comprise two different holders, one placed more distal than the other, forming two at least substantially closed loops. The adjustment device may be adapted to rotate the holders in opposite directions relative to each other. With interconnecting means, for example flexible bands between the different holders, a restriction will occur between the holders when they are rotated.

In all of the above-described embodiments of the invention the adjustment device is conveniently operated by any suitable motor, preferably an electric motor, which may be fixed directly to or be placed in association with the restriction device. Alternatively the motor may be located remote from the restriction device, advantageously in the abdomen or subcutaneously. In the latter alternative the motor is advantageously connected to the adjustment device by a flexible power transmission conduit to permit a suitable positioning of the motor in the abdomen of the patient. The motor may be manually activatable, for example by an implantable switch.

In some of the above-described embodiments of the invention, however, the adjustment device may conveniently be operated by a hydraulic operation device, which preferably is manually activatable. The hydraulic operation device may advantageously include hydraulic servo means to facilitate manual activation. As an alternative, the hydraulic device may be powered by an electric motor, which may be manually activatable or controlled by remote control means. The components of such a hydraulic operation device may be placed in association with the restriction member and/or be located at a suitable place in the abdomen or be subcutaneously implanted.

More specifically, a reservoir may be provided containing a predetermined amount of fluid for supplying the hydraulic

operation device with fluid. The reservoir defines a chamber for the predetermined amount of fluid and the hydraulic operation device changes the volume of the chamber. The hydraulic operation device may comprise first and second wall portions of the reservoir, which are displaceable relative to each other to change the volume of the chamber of the reservoir. The first and second wall portions of the reservoir may be designed to be displaceable relative to each other by manual manipulation thereof, preferably to permit manual pushing, pulling or rotation of any of the wall portions in one direction. Alternatively, the wall portions may be displaceable relative to each other by magnetic means (such as a permanent magnet and magnetic material reed switch, or other known or conventional magnetic devices), hydraulic means or electrical control means such as an electric motor. The magnetic means, hydraulic means, or electrical control means may all be activated by manual manipulation, preferably using a subcutaneously located manually manipulatable device. This control may be indirect, for example via a switch.

The hydraulic operation device may operate the adjustment device with fluid from the reservoir in response to a predetermined first displacement of the first wall portion of the reservoir relative to the second wall portion of the reservoir, to increase the size of the restriction opening, and to operate the adjustment device with fluid from the reservoir in response to a predetermined second displacement of the first wall portion of the reservoir relative to the second wall portion of the reservoir, to decrease the size of the restriction opening. In this embodiment, no pump is used, only the volume of the reservoir is varied. This is of great advantage compared to the solution described below when a pump is used to pump fluid between the reservoir and the adjustment device because there is no need for a non-return valve and it

is still possible to have fluid going both to and from the reservoir.

As an alternative, the hydraulic operation device may comprise a pump for pumping fluid between the reservoir and the adjustment device. The pump may pump fluid both to and away from the adjustment device, or hydraulic means controlling the adjustment device. A mechanical manual solution is proposed in which it is possible to pump in both directions just by pushing an activating member in one direction. Another alternative is a pump pumping in only one direction and an adjustable valve to change the direction of fluid to either increase or decrease the amount of fluid in the reservoir. This valve may be manipulated manually, mechanically, electrically, magnetically, or hydraulically. Any kind of motor could of course be used for all the different operations as well as wireless remote solutions. The pump may comprise a first activation member for activating the pump to pump fluid from the reservoir to the adjustment device and a second activation member for activating the pump to pump fluid from the adjustment device to the reservoir. The activation members may be operable by manual manipulation, preferably to permit manual pushing, pulling or rotating thereof in one direction. Suitably, at least one of the activation members is adapted to operate when subjected to an external pressure exceeding a predetermined magnitude.

Alternatively, at least one of the first and second activating members may be operable by magnetic means, hydraulic means or electrical control means such as an electric motor. The magnetic means, hydraulic means, or electrical control means may all be activated by manual manipulating means preferably located subcutaneously. This activation may be indirect, for example via a switch.

Advantageously, especially when manual manipulation means are used, a servo means could be used. With servo means less force is needed for operating the adjustment device. The term "servo means" encompasses the normal definition of a servo mechanism, *i.e.* an automatic device that controls large amounts of power by means of very small amounts of power, but may alternatively or additionally encompass the definition of a mechanism that transfers a weak force acting on a moving element having a long stroke into a strong force acting on another moving element having a short stroke. The servo means may comprise a motor, preferably an electric motor, which may be reversible.

Alternatively, a reverse servo may be employed. The term "reverse servo" is to be understood as a mechanism that transfers a strong force acting on a moving element having a short stroke into a weak force acting on another moving element having a long stroke; i.e. the opposite function of the above-defined alternative mechanism of a normal servo mechanism. A first closed hydraulic system that controls another closed hydraulic system in which hydraulic means of the adjustment device is incorporated may be used. Minor changes in the amount of fluid in a smaller reservoir of the first system could then be transferred by the reverse servo into major changes in the amount of fluid in a larger reservoir in the second system. In consequence, the change of volume in the larger reservoir of the second system affects the hydraulic means of the adjustment device. For example, a short stroke that decreases the volume of the smaller reservoir will cause the larger reservoir to supply the adjustment device with a large amount of hydraulic fluid, which in turn results in a long mechanical adjustment stroke on the restriction device. The great advantage of using such a reverse servo is that the larger volume system could be placed

inside the abdomen or retroperitoneum where there is more space and still it would be possible to use manual manipulation means of the smaller system subcutaneously. The smaller reservoir could be controlled directly or indirectly by a fluid supply means. The fluid supply means may include another small reservoir, which may be placed subcutaneously and may be activated by manual manipulation means. Both the servo and reverse servo may be used in connection with all of the various components and solutions described in the present specification.

Preferably, the reverse servo comprises hydraulic means and a main fluid supply reservoir and eventually an additional fluid supply reservoir. Both reservoirs define a chamber containing hydraulic fluid, and the hydraulic means comprises first and second wall portions of the main fluid supply reservoir, which are displaceable relative to each other to change the volume of the chamber of the main fluid supply reservoir. The hydraulic means may control the adjustment device indirectly, e.g. via an increased amount of fluid in the main fluid supply reservoir, in response to a predetermined first displacement of the first wall portion of any of the reservoirs relative to the second wall portion of the reservoir to restrict the food passageway, and to control the adjustment device in response to a second displacement of the first wall portion of any reservoir relative to the second wall portion, to indirectly adjust the restriction device to enlarge the food passageway. The wall portions of the reservoirs may be designed to be displaceable relative to each other by manual manipulation thereof or be displaceable relative to each other by manually pushing, pulling or rotating any of the wall portions of the reservoir in one direction. Alternatively, the wall portions of the main fluid supply reservoir may be displaceable relative to each other by

magnetic means, hydraulic means or electric control means including an electric motor.

The magnetic means, hydraulic means, or electrical control means may all be activated by manually manipulated means preferably located subcutaneously. This control may be indirect for example via a switch.

Even in the broadest embodiment of the invention the adjustment device may comprise a servo means. The servo means may comprise a hydraulic operation means, an electrical control means, a magnetic means, mechanical means or a manual manipulation means. The hydraulic operation means, electrical control means, mechanical means or magnetic means may be activated by manual manipulating means. Using a servo system will save the use of force when adjusting the adjustment device that may be of importance in many applications, for example when a battery cannot put out enough current although the total energy in the battery is more than enough to power the system.

The hydraulic fluid used by the operation device in any of the above embodiments may be of a kind that changes viscosity when it is exposed to energy different from thermal energy. For example, the viscosity of the hydraulic fluid may change when the fluid is exposed to electric energy. It should be understood that the word fluid also could incorporate gas or air in all applications.

In accordance with a preferred embodiment of the invention, the apparatus comprises implantable electrical components including at least one, or only one single voltage level guard and a capacitor or accumulator, wherein the charge and discharge of the capacitor or accumulator is controlled by use of the voltage level guard. As a result, there is no need for any implanted current detector and/or charge level

detector for the control of the capacitor, which makes the apparatus simple and reliable.

All solutions may be controlled by a wireless remote control for non-invasively controlling the adjustment device. The remote control may advantageously be capable of obtaining information on the size of the restriction opening or other information related to the implanted components of the treatment apparatus and to command the adjustment device to adjust the restriction member in response to obtained information. With the remote control the treatment apparatus of the invention is conveniently controlled to adjust the restriction device, which controls the cross-sectional area of the food passageway and wherein the restriction device is operable to open and close the food passageway.

The device according may further comprise a pressure sensor for directly or indirectly sensing the pressure against the restriction device and the control device may control the restriction device in response to signals from the pressure sensor. The post-operation adjustment device preferably is adapted to non-invasively adjust the restriction device to change the size of the cross-sectional area. The pressure sensor may be any suitable known or conventional pressure sensor such as shown in U.S. patents 5540731, 4846181, 4738267, 4571749, 4407296 or 3939823; or an NPC-102 Medical Angioplasty Sensor.

The device may further comprise an implanted energy transforming device for transforming wireless energy directly or indirectly into kinetic energy for operation of the restriction device. The energy transforming device may, preferably directly, transform the wireless energy in the form of sound waves into electric energy for operation of the restriction device. Suitably the energy transforming device

comprises a capacitor adapted to produce electric pulses from the transformed electric energy.

The remote control permits adjustment of the restriction device any time after the operation, so that the patient may get rid of problems with belching, swallowing etc. The patient can conveniently open up the restriction opening somewhat more when eating and close the restriction opening at night, when going to bed. This new adjustment procedure available to a patient provided with the device of the invention is a great advantage compared to the prior art.

The apparatus of the invention may further comprise an energy transfer means for wireless transfer of energy from outside the patient's body to the adjustment device and/or other energy consuming implantable components of the apparatus. The energy transfer means may be adapted to intermittently transfer the energy, preferably electric energy, in the form of a train of energy pulses for direct use in connection with the energising of the energy consuming components of the apparatus. An implanted capacitor having a capacity less than 0,1 μF may be used for producing the train of energy pulses.

A motor may be implanted for operating the adjustment device, wherein the energy transfer means is adapted to directly power the motor with transferred energy. Alternatively, or in combination with the motor, a pump may be implanted for operating the adjustment device, wherein the energy transfer means is adapted to transfer wireless energy in the form of electromagnetic waves for direct power of the pump. Preferably, the pump is not a plunger type of pump, but may comprise a peristaltic or membrane pump.

The energy transfer means preferably transfers wireless energy in the form of electromagnetic waves. However, for safety radio waves may be excluded.

Alternatively, the energy transferred by the energy transfer means may comprise an electric field or a magnetic field.

Most preferred, the energy transferred by the energy transfer means comprises a signal.

Preferably, the wireless remote control comprises a separate signal transmitter or receiver and a signal receiver or transmitter implanted in the patient. For example, the signal transmitter and signal receiver may transmit and receive a signal in the form of digital pulses, which may comprise a magnetic or electric field. Alternatively, which is preferred, the signal transmitter and signal receiver may transmit and receive an electromagnetic wave signal, a sound wave signal or a carrier wave signal for a remote control signal. The receiver may comprise an implanted control unit for controlling the adjustment device in response to a control signal from the signal transmitter.

The apparatus of the invention may further comprise an implanted energiser unit for providing energy to energy consuming implanted components of the apparatus, such as electronic circuits and/or a motor for operating the adjustment device. The apparatus may comprise an external energy transmitter for transmitting wireless energy, wherein the energiser unit is adapted to transform the wireless energy into electric energy. An implanted electric motor may operate the adjustment device and the energiser unit may be adapted to power the electric motor with the electric energy transformed from the wireless energy.

The energiser unit may comprise a battery and a switch operable by the wireless energy transmitted by the external transmitter, for connecting the battery to the implanted energy consuming components of the apparatus in an "on" mode when the switch is powered by the wireless energy and to keep

the battery disconnected from the energy consuming components in a "standby" mode when the switch is not powered.

The control unit may power such an implanted motor with energy provided by the energiser unit in response to a control signal received from the signal transmitter. Any known or conventional signal transmitting or signal receiving device that is suitable for use with a human or mammal patient may be provided as the signal transmitter or signal receiver.

Generally, all of the above mentioned signals may comprise an electromagnetic wave signal, such as an infrared light signal, a visible light signal, a laser light signal, a micro wave signal, or a sound wave signal, such as an ultrasonic wave signal or an infrasonic wave signal, or any other type of wave signals. The signal may also comprise electric or magnetic fields, or pulses. All of the above-mentioned signals may comprise digital signals. The control signal may be carried by a carrier signal, which may be the same as the wireless energy signal. Preferably, a digital control signal may be carried by an electromagnetic wave signal. The carrier signal or control signal may be amplitude or frequency modulated.

The motor may be any type of motor, such as a pneumatic, hydraulic or electric motor and the energiser unit may power the motor with pressurized gas or liquid, or electric energy, depending on the type of motor. Where the motor is an electric motor, it may power pneumatic or hydraulic equipment.

The energiser unit may comprise a power supply and the control unit may power the motor with energy from the power supply. Preferably, the power supply is an electric power supply, such as a battery, and the motor is an electric motor. In this case, the battery also continuously powers at least a part of the circuitry of the signal receiver in a standby mode between adjustments, in order to keep the signal receiver

prepared for receiving signals transmitted from the signal transmitter.

The energiser unit may transform energy from the signals, as they are transmitted to the signal receiver, into electric energy for powering the implanted electronic components. For example, the energiser unit may transform the energy from the signals into a direct or alternating current.

In case there is an implanted electric motor for operating the adjustment device the energiser unit may also power the motor with the transformed energy. Advantageously, the control unit directly powers the electric motor with electric energy, as the energiser unit transforms the signal energy into the electric energy. This embodiment is particularly simple and does not require any recurrent invasive measures for exchanging empty power supplies, such as batteries, that is required in the first embodiment described above. The motor may also be directly powered with wirelessly transmitted electromagnetic or magnetic energy in the form of signals, as the energy is transmitted. All the various functions of the motor and associated components described in the present specification may be used where applicable.

For adjustment devices of the type that require more, but still relatively low, power for their operation, the energiser unit may comprise a rechargeable electric power supply for storing the electric energy obtained and the control unit may power the electric motor with energy from the rechargeable electric power supply in response to a control signal received from the signal transmitter. In an initial charging step the rechargeable power supply can be charged over a relatively long time (*e.g.* a few seconds up to a half hour) without powering the electric motor. In a following operating step, when the power supply has been charged with sufficient energy, the control unit powers the electric motor with energy from

the charged power supply to operate the adjustment device, so that a desired change of the cross-sectional area of the food passageway is achieved. If the capacity of the power supply is insignificant to achieve the necessary adjustment in one single operating step, the above steps may conveniently be repeated until the desired adjustment is achieved.

The electric power supply suitably comprises an inexpensive simple capacitor. In this case, the electric motor may be a stepping motor. In all cases the motor may be able to perform a reversing function.

The signal transmitter may transmit an electromagnetic control signal and the energiser unit may draw radiant energy from the electromagnetic wave signal, as this signal is transmitted to the signal receiver, and may transform the radiant energy into electric energy.

Alternatively, the energiser unit may comprise a battery, an electrically operable switch for connecting the battery to the signal receiver in an on mode when the switch is powered and for keeping the battery disconnected from the signal receiver in a standby mode when the switch is not powered, and a rechargeable electric power supply for powering the switch. The control unit may power the electric motor with energy from the battery in response to a control signal received from the signal transmitter, when the switch is in its on mode. Advantageously, the energiser unit may transformer wave energy from the control signal, as the latter is transmitted to the signal receiver, into a current for charging the rechargeable electric power supply, which suitably is a capacitor. Energy from the power supply is then used to change the switch from off (standby mode) to on. This embodiment is suited for adjustment devices of the type that require relatively high power for their operation and has the advantage that the electronic circuitry of the signal receiver does not have to

be powered by the battery between adjustments. As a result, the lifetime of the battery can be significantly prolonged. Magnetic, manual or electric energy may be used for switching the switch.

As an example, the signal transmitter may transmit an electromagnetic wave signal and the energiser unit may draw radiant energy from the electromagnetic wave signal, as the latter is transmitted to the signal receiver, and may transform the radiant energy into electric current. The energiser unit suitably comprises a coil of the signal receiver for inducing an alternating current as the electromagnetic wave signal is transmitted through the coil and a rectifier for rectifying the alternating current. The rectified current is used for charging the rechargeable power source.

Alternatively, the signal transmitter and receiver may solely be used for control signals and a further pair of signal transmitter and receiver may be provided for transferring signal energy to implanted components. By such a double system of signal transmitters and receivers the advantage is obtained that the two systems can be designed optimally for their respective purposes, namely to transmit control signals and to transfer energy from signals. Accordingly, the device may further comprise an external energy transmitter for transmitting wireless energy, wherein the energiser unit comprises a battery and an operable switch for connecting the battery to the signal receiver in an on mode when the switch is powered and to keep the battery disconnected from the signal receiver in a standby mode when the switch is not powered, the external energy transmitter for powering said switch. Suitably, the energy transmitter may directly power the switch with the wireless energy to switch into the on mode.

As should be realized by a skilled person, in many of the above-described embodiments of the invention the adjustment device may be operated by control means or manual manipulation means implanted under the skin of the patient, such as a pump, an electrical switch or a mechanical movement transferring means. In the manual embodiment it is not necessary to use a motor for operating the adjustment device.

In embodiments including hydraulic transmission means, an injection port connected to the hydraulic means may be provided for enabling, normally single, once-and-for-all, calibration of the amount of fluid in the hydraulic system.

In all embodiments a motor may be operatively connected to the adjustment device. A reversing device may be implanted in the patient for reversing the motor.

In all applications the adjustment device preferably adjusts the restriction device in a non-manual manner without touching the skin of the patient.

The adjustment device may be adapted to hydraulically adjust the restriction device by using hydraulic means which is devoid of hydraulic fluid of the kind having a viscosity that substantially increases when exposed to heat or a magnetic field, *i.e.* the hydraulic fluid would not become more viscous when exposed to heat or influenced by magnetic forces.

All the above-described various components, such as the motor, pump and capacitor, may be combined in the different embodiments where applicable. Also the various functions described in connection with the above embodiments of the invention may be used in different applications, where applicable.

All the various ways of transferring energy and controlling the energy presented in the present specification may be practised by using all of the various components and solutions described.

The invention also provides a method for treating heartburn and reflux disease, comprising (a) surgically implanting in the abdomen of a patient suffering from heartburn and reflux disease an adjustable restriction device which forms a food passageway having a restricted cross-sectional area in the esophagus or in the stomach close to the cardia, and (b) in a non-invasive procedure mechanically adjusting the restriction device to change the size of the cross-sectonal area of the food passageway.

The adjustment device may in all cases be mechanically operated and/or operated in a non-manual manner and be energised by the provision of a source of energy from which energy is released by control means from outside the patient's body to energise the adjustment and/or restriction device.

The invention also provides a surgical method for laparascopically implanting an adjustable restriction device of a heartburn and reflux disease treatment apparatus for forming a food passageway having a restricted cross-sectional area in the esophagus or stomach immediately close to the cardia, the method comprising: (a) Insufflating the abdomen of a patient to form a pneumoperitoneum. (b) Introducing at least one laparascopic trocar into the abdomen. (c) Using a dissecting tool inserted through the laparascopic trocar, dissecting the region of the esophagus or stomach adjacent or above the bursa omentalis. And (d) introducing the restriction device in the abdomen and applying it on the esophagus or stomach. This method further comprises after (a)-(d), (e) post-operatively adjusting the restriction device in a non-invasive procedure to change the cross-sectional area of the food passageway.

The invention is described in more detail in the following with reference to the accompanying drawings, in which

FIGURE 1 is a schematic sectional view of a preferred first embodiment of the heartburn and reflux disease treatment apparatus in accordance with the invention;

FIGURES 2 and 3 are cross-sectional views taken along the lines II-II and III-III, respectively, of FIGURE 1;

FIGURES 4 and 5 schematically show two alternative designs of the embodiment of FIGURE1;

FIGURE 6 schematically illustrates a motor arrangement for the design according to FIGURE 5;

FIGURE 7 is a schematic sectional view of a second embodiment of the apparatus in accordance with the invention;

FIGURE 8 schematically illustrates a hydraulic transmision conduit for the embodiment of FIGURE 7;

FIGURE 9 is a schematic sectional view of a third embodiment of the apparatus in accordance with the invention;

FIGURE 10 is a modification of the embodiment of FIGURE9;

FIGURE 11 is a schematic view of a fourth embodiment of the apparatus in accordance with the invention;

FIGURES 12 and 13 are enlarged details of the embodiment of FIGURE 11;

FIGURE 14 is a cross-section along the line XIV-XIV of FIGURE 11;

FIGURE 15 is a schematic view of a fifth embodiment of the apparatus in accordance with the invention;

FIGURE 16 is an enlarged detail of FIGURE 15;

FIGURE 17 is a cross-section along the line XVII-XVII of FIGURE 15;

FIGURES 18 to 21 are schematic sectional views of a sixth, seventh, eighth and ninth embodiments, respectively, of the apparatus in accordance with the invention;

SDOCID: <WO___0149245A2_I_>

FIGURES 22 and 23 illustrate a fully open and a reduced restriction opening, respectively, of the embodiment of FIGURE 21;

FIGURE 24 is a schematic view of a tenth embodiment of the apparatus in accordance with the invention;

FIGURE 25 is an enlarged detail of the embodiment of FIGURE 24;

FIGURES 26 and 27 illustrate a fully open and a reduced restriction opening, respectively, of the embodiment of FIGURE 24;

FIGURE 28 schematically illustrates a cushion arrangement for protecting the stomach or esophagus of the patient;

FIGURE 29A-D is a block diagram of four different principal embodiments of the invention;

FIGURE 30A-D are cross-sectional views of a pump mechanism according to FIGURE 29C, which pumps fluid in opposite directions by mechanically pushing a wall portion in only one direction;

FIGURE 31 is a cross-sectional view of a reservoir having a variable volume controlled by a remote control motor, in accordance with a particular embodiment of the principal embodiment shown in FIGURE 29B or 30B;

FIGURE 32 is a cross-sectional view of a reservoir having a variable volume adjustable by manual manipulation, in accordance with a particular embodiment of the principal embodiment shown in FIGURE 29B or 29D;

FIGURE 33A is a front view of a hydraulic, pneumatic or mechanical reverse servo system in accordance with a particular embodiment of the principal embodiment shown in FIGURE 29D;

Fig 33B is a cross-sectional view taken along line VB-VB of Fig 33A;

FIGURE 34 is a block diagram illustrating remote control components of the apparatus of the invention;

FIGURE 35 is a schematic view of a circuitry used for the system of the block diagram of FIGURE34;

FIGURES 36A and 36B are schematic views of an eleventh embodiment of the apparatus in accordance with the invention;

FIGURES 37A and 37B are schematic views of a twelfth embodiment of the apparatus in accordance with the invention;

FIGURE 38 is a schematic view of a thirteenth embodiment of the apparatus in accordance with the invention;

FIGURES 39A, 39B and 39C are a schematic front view and schematic sectional views, respectively, of a fourteenth embodiment of the apparatus in accordance with the invention;

FIGURES 40A through 44B are five modifications of the embodiment of FIGURES 39A-39C; and

FIGURE 45 illustrates the apparatus in accordance with the invention implanted in a patient.

Referring to the drawing figures, like reference numerals designate identical or corresponding elements throughout the several figures.

The invention is described in more detail in the following with reference to the accompanying drawings, in which

Figs. 1-3 show a preferred embodiment of the heartburn and reflux disease treatment apparatus of the invention comprising a restriction apparatus having an elongated restriction member in the form of a circular resilient core 2 with two overlapping end portions 4,6. The core 2 defines a substantially circular restriction opening and is enclosed in an elastic soft hose 8 except at a releasable and lockable joint 10 of the core 2, which when released enables application of the core 2 with its hose 8 around the esophagus

or stomach of a patient. The materials of all of these elements are bio-compatible so that the patient s body will not reject them. A post-operation mechanical adjustment device 12 for mechanically adjusting the longitudinal extension of the core 2 to change the size of the restriction opening comprises a drive wheel 14 in frictional engagement with the overlapping end portions 4,6 of the core 2. The drive wheel 14 is journalled on a holder 16 placed in the hose 8 and provided with two counter pressure rollers 18,20 pressing the respective end portions 4, 6 of the core 2 against the drive wheel 14 to increase the frictional engagement therebetween. An electric motor 22 is connected to the drive wheel 14 via a long flexible drive shaft 24 and is moulded together with a remote controlled power supply unit 26 in a body 28 of silicone rubber. The length of the flexible drive shaft 34 is selected so that the body 28 can be placed in a desired position in the patient's body, suitably in the abdomen.

If some time after the operation the patient needs an adjustment of the restriction opening of the core 2, the power supply unit 26 is controlled to power the electric motor 22 either to turn the drive wheel 14 in one direction to reduce the diameter of the core 2 or to turn the drive wheel 14 in the opposite direction to increase the diameter of the core 2.

Alternatively, a rack gear may be formed on one of the end portions 4,6 of the core 2 and the drive wheel 14 may be replaced by a drive gear wheel connected to the other end portion of the core 2 and in mesh with the rack gear.

Fig.4 shows an embodiment of the invention which is identical to the embodiment of FIGURES 1-3, except that the motor 22 is encapsulated in a lateral protrusion 30 of the hose 8 so that it is fixed to the core 2 and has a short drive shaft 32 onto which the drive wheel 14 is mounted, the motor

22 being positioned relative to the circular core 2 such that the drive shaft 32 extends radially thereto.

Fig. 5 shows an embodiment of the invention which likewise is identical to the embodiment of Figs. 1-3, except that the motor 22 is encapsulated in the hose 8 so that it is fixed to the core 2 and has a short drive shaft 32, the motor 22 being positioned relative to the core 2 such that the drive shaft 32 extends substantially tangentially to the circular core 2. There is an angular gearing 34 connecting the drive shaft 32 to the drive wheel 14.

Fig. 6 shows a suitable arrangement for the motor 22 in the embodiment of Fig. 5, comprising a first clamping member 36 secured to one end portion of the core 2 and a second clamping member 38 secured to the other end portion 6 of the core 2. The motor 22 is secured to the first clamping member 36 and is operatively connected to a worm 40 via a gear transmission 42. The worm 40 is journalled at its opposite ends on holders 44 and 46, which are rigidly secured to the clamping member 36 and the motor 22, respectively. The second clamping member 38 has a pinion in mesh with the worm 40. When the motor 22 is powered the worm 40 rotates and will thereby pull the end portion 6 of the core 2 in one or the opposite longitudinal direction, so that the diameter of the substantially circular core 2 is either increased or decreased.

Fig. 7 shows an embodiment of the invention in which the elongated restriction member comprises a core 48 and a helical spring 50. A spring contracting means in the form of a flexible pulling member 52, *i.e.* a string, wire or cable, is connected to the core 48 at one end thereof and extends through the helical spring 50. A hydraulic motor in the form of a cylinder/piston unit 54 is adapted to pull the flexible pulling member 52 to contract the helical spring 50 against an

arresting member 56, which is fixed relative to the core 48. A tube 58 hinged to the arresting member 56 extends between the cylinder/piston unit 54 and the arresting member 56, the flexible pulling member 52 running through the tube 58 and being connected to the piston of the cylinder/piston unit 54. Fig. 8 shows a similar embodiment in which a hydraulic transmission conduit 59 is provided between two piston-cylinder assemblies 54, for use as the hydraulic motor in Fig. 7.

Fig. 9 shows an embodiment of the invention in which the restriction member comprises two elongated helical springs 60 and 62 having free ends, and a body 64 to which the springs 60,62 are nonrotatably secured at their opposite ends. The body 64 comprises two separate parts secured to opposite end portions of the enclosing elastic hose 8 and is designed with a releasable and lockable joint between the separate parts. An adjustment device in the form of a drive shaft 66 has two opposite end portions connected to the helical springs 60,62, respectively, at their free ends. The coils of the springs 60,62 form left and right hand helices, respectively. A motor 68 is adapted to rotate the drive shaft 66 in one direction to enlarge the coils of the helical springs 60,62 to longitudinally contract the springs 60,62 and to rotate the drive shaft 66 in the opposite direction to reduce the size of the coils of the springs 60,62 to longitudinally extend the springs 60,62. Thus, the elongated helical springs 60,62 defines a restriction opening, the size of which is increased when the springs 60,62 are extended and decreased when the springs 60,62 are contracted.

Fig. 10 shows an embodiment according to the invention which is identical to the embodiment of Fig. 9, except that the adjustment decice comprises a gearing having an input shaft 72 and two opposite aligned output shafts 74 and 76 connected to

the helical springs 60 and 62, respectively, at their free ends. The input shaft 72 is connected to the output shafts 74,76 such that they rotate at opposite directions upon rotation of the input shaft 72. The coils of the springs 60, 62 form the same helices.

Figs. 11-14 show an embodiment of the apparatus of the invention in which a hydraulic motor comprises two interconnected cylinders 78 and 80 and two pistons 82 and 84 in the respective cylinders 78,80. The cylinders 78,80 have a common fluid supply inlet member 86, which together with the cylinders 78,80 takes the shape of a Y-pipe. The restriction member comprises an elongated resilient arcuate core 88. The adjustment device comprises two bars 90 and 92 secured to opposite ends of the core 88 and connected to the pistons 82 and 84, respectively. The core 88 defines a restriction opening and is provided with a releasable and lockable joint 94 (Fig. 13) to permit application of the core 88 around the esophagus or stomach. The core 88 and the cylinders 90,92 are enclosed by a soft elastic hose 96 except at the joint 94 and the inlet member 86. The hose 96 has an outer tubular wall 98 and a central coaxial inner tubular wall 100, which is fixed to the outer wall 98 by spoke members 102 (Fig. 14). The core 88 is loosely fit in the inner tubular wall 100. By supplying fluid to or withdrawing fluid from the inlet 86 the pistons 82 and 84 will move towards or from each other, so that the restriction opening defined by the core 88 is changed by the longitudinal displacement of the bars 90,92.

Figs. 15-17 show an embodiment of the invention which is identical to the embodiment of Figs. 11-14, except that the adjustment device comprises an elongated voltage responsive element 104 secured to the opposite ends of the core 88, so that the core 88 and the element 104 form the restriction member. The element 104 is capable of bending inwardly into a

bow in response to a voltage applied across the element 104. The radius of curvature of said bow is adjustable by changing the level of the voltage applied to element 104.

Fig. 18 shows an embodiment of the invention comprising a loop forming means in the form of a substantially rigid outer circular element 106 with a releasable and lockable joint 108. In this embodiment the restriction member comprises an elastic inner circular element 110 formed by the innermost wall portion of an elastic hose 112 extending along the outer element 106. The inner circular element 110 is disposed concentrically within the outer circular element 106. The adjustment device comprises a plurality of threads 114 secured to the elastic inner element 110 along the circumference thereof and running from the inner element 110 via guide members 116 attached to the outer element 106. By pulling all the threads 114 the inner elastic element 110 is pulled under expansion radially outwardly towards the outer element 106.

Fig. 19 shows an embodiment which is identical to the embodiment of Fig, 9, except that it comprises a loop forming means in the form of a substantially rigid outer circular element 118 supporting the helical springs 60,62, and a soft elastic inner wall 120 extending along the springs 60,62. When the motor 68 rotates the helical springs 60, 62 in a direction that enlarges the coils of the springs 60,62, the coils are forced by the rigid outer element 118 to expand radially inwardly thereby reducing the size of the restriction opening formed by the circumferential confinement surface of the restriction member (springs 60,62 and body 64).

Fig. 20 shows an embodiment of the invention in which a restriction member comprises a plurality of arcuate lamellae 122 arranged like the conventional adjustable aperture mechanism of a camera. The adjustment device, not shown, is conventional and is operated by a motor 124 to adjust the

lamellae 122 to change the size of an restriction opening defined by the lamellae 122.

Figs. 21-23 show an embodiment of the invention in which a restriction member comprises two semi-circular elements 126 and 128 which are hinged together such that the semi-circular elements 126,128 are swingable relative to each other between a fully open state in which they substantially form a circle, illustrated in Fig, 22 and an angular state, in which the size of the restriction opening defined by the semi-circular elements 126,128 is reduced, illustrated in Fig, 23. The adjustment device, not shown, is conventional and is operated by a motor 130 to swing the semi-circular elements 126,128 relative to each other.

Figs. 24-27 show an embodiment of the invention in which a restriction member comprises an elastic belt 130 forming a circle and having a substantially oval cross-section. The restriction member 130 is provided with a releasable and lockable joint 132. An elastic double walled hose 134 encloses the belt 130 except at the joint 132. The adjustment device, not shown, is conventional and is operated by a motor 136 to turn the belt 130 around the longitudinal extension thereof between a fully open state, in which the inner broader side of the belt 130 forms a substantially cylindrical surface, illustrated in Fig. 26, and a reduced open state, in which the inner broader side of the belt 130 forms a substantially conical surface, illustrated in Fig. 27.

Fig. 28 schematically illustrates a cushion arrangement for protecting the esophagus or stomach, comprising a plurality of cushions 138 disposed in series along a substantially circular holding member 140. This cushion arrangement may be utilized in any of the above described embodiments of the invention.

Figs. 29A-D provide a block diagram of four different hydraulic transmission configurations. Fig. 29A shows an adjustment device 202, a separate reservoir 204, a one way pump 206 and an alternate valve 208. Fig. 29B shows the adjustment device 202 and an adjustable reservoir 210. Fig. 29C shows the adjustment device 202, a two way pump 212 and the reservoir 204. Fig. 30D shows a servo system with a first closed system controlling a second system. The servo system comprises the adjustable reservoir 210 and a passive adjustable reservoir 214. Any of the reservoirs can be the active reservoir, either the servo reservoir 210 or the fluid supply reservoir 214. The reservoir 214 controls a larger adjustable reservoir 216 which is used for the operation of the adjustment device 202 for changing the restriction opening of the restriction member.

Figs. 30A-D are cross-sectional views of a pump mechanism adapted to pump fluid in both directions only by mechanically pushing a separate sealing wall portion 218 in one direction. Fig 30A shows a piston 220 pushed forwards against a spring 222 towards the wall portion 218 and located in a pump housing 224 conducting fluid from a right upper fluid passage 226 of the housing 224 to a left fluid passage 228 of the housing 224. A main valve 230 is open and a nonreturn valve 232 is closed. Fig. 30B illustrates the first pump movement in which the piston 220 has moved forwards and reaches the wall portion 218. Fig. 30C illustrates how the piston 220 moves backwards by the action of the spring 222. The main valve 230 is now closed and the nonreturn valve 232 is open for fluid from the right upper passage 226. Fig. 30D illustrates how the piston 220 is moved further downwards from its position according to Fig. 30B while pushing the wall portion 218 downwards against a second spring 234 that is stronger than spring 222, so that fluid escapes from a right lower fluid passage 236. When

moving the piston 220 backwards from the position of Fig. 30D, fluid enters the left fluid passage 228 and a valve 238 in the lower right fluid passage 236 closes.

Fig 31 is a cross-sectional view of a reservoir 240 defining a chamber 242, the volume of which is variable and is controlled by a remote controlled motor 244, in accordance with Fig. 29B or 29D. The reservoir 240 and the motor 244 are placed in a housing 246. The chamber 242 is varied by moving a large wall 248. The wall 248 is secured to a nut 250, which is threaded on a rotatable spindle 252. The spindle 252 is rotated by the motor 244 via an angular gearing, which comprises two conical gear wheels 254 and 256 in mesh with each other. The motor 244 is powered by a battery 258 placed in the housing 246. A signal receiver 260 for controlling the motor 244 is also placed in the housing 246. Alternatively, the battery 258 and the signal receiver 260 may be mounted in a separate place. The signal receiver may comprise any known or conventional means which is capable of receiving a control signal and then operating the motor 244.

Fig. 32 is a cross-sectional view of a reservoir 262 defining a chamber 264, the volume of which is variable and is controlled by manual manipulation. A gable wall portion 266 of an open ended inner cylindrical housing 68 is adapted to be pushed downwards to fit in a desired locking groove 270 of a plurality of locking grooves 270 on the mantle wall of the cylindrical housing 268, to reduce the volume of the chamber 64. The inner cylindrical housing 268 is suspended by springs 272 and is telescopically applied on an outer cylindrical housing 274. When pushing the inner cylindrical housing 268 it moves downwards relative to the outer cylindrical housing 274 causing the gable wall portion 266 to release from the locking groove 270 and move upwards relative to the inner cylindrical housing 268. When the inner housing 268 is moved upwardly by

the action of the springs 272 the volume of the chamber 264 is increased.

Fig. 33A and 33B show a servo means comprising a main ring-shaped fluid reservoir 276 defining a chamber 278, the volume of which is variable. Centrally positioned in the main ring-shaped reservoir 276 there is a servo fluid reservoir 280 defining a chamber 282, the volume of which is variable. The chamber 282 of the servo reservoir 280 is significantly smaller than the chamber 278 of the main reservoir 276. The two reservoirs 276 and 280 are situated between two opposite separate walls 284 and 286, and are secured thereto. When changing the amount of fluid in the servo reservoir 280, the two opposite walls 284,286 are moved towards or away from each other, whereby the volume of the chamber 278 of the main reservoir 276 is changed.

Fig. 34 shows the basic parts of a remote control system of the apparatus of the invention including a motor, for instance the electric motor 22. In this case, the remote control system is based on the transmission of electromagnetic wave signals, often of high frequencies in the order of 100 kHz - 1 gHz, through the skin 330 of the patient. In Fig. 34, all parts placed to the left of the skin 330 are located outside the patient's body and all parts placed to the right of the skin 330 are implanted in the patient's body.

An external signal transmitting antenna 332 is to be positioned close to a signal receiving antenna 334 implanted in the patient's body close to the skin 330. As an alternative, the receiving antenna 334 may be placed for example inside the abdomen of the patient. The receiving antenna 334 comprises a coil, approximately 1-100 mm, preferably 25 mm in diameter, wound with a very thin wire and tuned with a capacitor to a specific high frequency. A small coil is chosen if it is to be implanted under the skin of the

patient and a large coil is chosen if it is to be implanted in the abdomen of the patient. The transmitting antenna 332 comprises a coil having about the same size as the coil of the receiving antenna 334 but wound with a thick wire that can handle the larger currents that is necessary. The coil of the transmitting antenna 332 is tuned to the same specific high frequency as the coil of the receiving antenna 334.

An external control unit 336 comprises a microprocessor, a high frequency electromagnetic signal generator and a power amplifier. The microprocessor of the control unit 336 is adapted to switch on/off the generator and to modulate signals generated by the generator to send digital information via the power amplifier and the antennas 332,334 to an implanted control unit 338. To avoid that accidental random high frequency fields trigger control commands, digital signal codes are used. A keypad placed on the external control unit 336 is connected to the microprocessor thereof. The keypad is used to order the microprocessor to send digital signals to either increase or decrease the size of the restriction opening defined by the loop of the restriction member (*e.g.* as described above). The microprocessor starts a command by applying a high frequency signal on the antenna 332. After a short time, when the signal has energized the implanted parts of the control system, commands are sent to increase or decrease the size of the restriction opening of the restriction member in predefined steps. The commands are sent as digital packets in the form illustrated below.

Start pattern, 8 bits	comman d, 8 bits	Count , 8 bits	Checksu m, 8 bits

The commands are sent continuously during a rather long time period (*e.g.* 30 seconds or more). When a new increase or decrease step is desired the Count byte is increased by one to allow the implanted control unit 338 to decode and understand that another step is demanded by the external control unit 336. If any part of the digital packet is erroneous, its content is simply ignored.

Through a line 340, an implanted energiser unit 326 draws energy from the high frequency electromagnetic wave signals received by the receiving antenna 334. The energiser unit 326 stores the energy in a power supply, such as a large capacitor, powers the control unit 338 and powers the electric motor 22 via a line 342.

The control unit 338 comprises a demodulator and a microprocessor. The demodulator demodulates digital signals sent from the external control unit 336. The microprocessor of the control unit 338 receives the digital packet, decodes it and, provided that the power supply of the energiser unit 326 has sufficient energy stored, sends a signal via a signal line 344 to the motor 22 to either increase or decrease the size of the restriction opening of the restriction member depending on the received command code.

Alternatively, the energy stored in the power supply of the energiser unit may only be used for powering a switch, and the energy for powering the motor 22 may be obtained from another implanted power source of relatively high capacity, for example a battery. In this case the switch is adapted to connect the battery to the control unit 338 in an "on" mode when said switch is powered by said power supply and to keep said battery disconnected from the control unit in a "standby" mode when the switch is not powered.

SDOCID: <WO__0149245A2_I_>

With reference to Fig. 35, the remote control system schematically described above will now be described in accordance with a more detailed embodiment. The external control unit 336 comprises a microprocessor 346, a signal generator 348 and a power amplifier 350 connected thereto. The microprocessor 346 is adapted to switch the signal generator 348 on/off and to modulate signals generated by the signal generator 348 with digital commands that are sent to implanted components of the apparatus of the invention. The power amplifier 350 amplifies the signals and sends them to the external signal transmitting antenna 332. The antenna 332 is connected in parallel with a capacitor 352 to form a resonant circuit tuned to the frequency generated by the signal generator 348.

The implanted signal receiving antenna coil 334 forms together with a capacitor 354 a resonant circuit that is tuned to the same frequency as the transmitting antenna 332. The signal receiving antenna coil 334 induces a current from the received high frequency electromagnetic waves and a rectifying diode 360 rectifies the induced current, which charges a storage capacitor 358. A coil 356 connected between the antenna coil 334 and the diode 360 prevents the capacitor 358 and the diode 360 from loading the circuit of the signal receiving antenna 334 at higher frequencies. Thus, the coil 356 makes it possible to charge the capacitor 358 and to transmit digital information using amplitude modulation.

A capacitor 362 and a resistor 364 connected in parallel and a diode 366 forms a detector used to detect amplitude modulated digital information. A filter circuit is formed by a resistor 368 connected in series with a resistor 370 connected in series with a capacitor 372 connected in series with the resistor 368 via ground, and a capacitor 374, one terminal of which is connected between the resistors 368,370 and the other

terminal of which is connected between the diode 366 and the circuit formed by the capacitor 362 and resistor 364. The filter circuit is used to filter out undesired low and high frequencies. The detected and filtered signals are fed to an implanted microprocessor 376 that decodes the digital information and controls the motor 22 via an H-bridge 378 comprising transistors 380,382,384 and 386. The motor 22 can be driven in two opposite directions by the H-bridge 378.

The microprocessor 376 also monitors the amount of stored energy in the storage capacitor 358. Before sending signals to activate the motor 22, the microprocessor 376 checks whether the energy stored in the storage capacitor 358 is enough. If the stored energy is not enough to perform the requested operation, the microprocessor 376 waits for the received signals to charge the storage capacitor 358 before activating the motor 22.

Figs. 36A and 36B show an embodiment of the apparatus of the invention comprising a restriction device 402 having an elongated flexible restriction member 404, such as a belt, a cord or the like. The flexible member 404 extends in a loop around the esophagus 406 (or stomach). (Alternatively, the flexible member 404 may comprise two separate parts on opposite sides of the esophagus.) One portion 404A of member 404 is attached to a frame 408 and another portion 404B of member 404 opposite portion 404A in the loop of the flexible member 404 is connected to an adjustment device 410, which is fixed to the frame 408. The adjustment device 410 pulls the flexible member 404 in the direction from portion 404A to squeeze esophagus between two opposite lengths of the flexible member 404 to thereby decrease the cross-sectional area in the esophagus (or stomach), see Fig. 36A, and releases the esophagus from the flexible member 404 to thereby increase the cross-sectional area in the esophagus 406, see Fig. 36B.

SDOCID: <WO___0149245A2_I_>

Figs. 37A and 37B show an embodiment of the apparatus of the invention comprising a restriction device 412 having two rigid plate or bar elements 414 on opposite sides of the esophagus 406 (or stomach). An adjustment device 416 moves the rigid elements 412 in parallel towards each other to squeeze the esophagus 406 between the rigid elements 412 to thereby decrease the cross-sectional area in the esophagus, see Fig. 37A, and moves the rigid elements 412 away from each other to increase the cross-sectional area in the esophagus 406, see Fig. 37B.

Fig. 38 shows an embodiment of the apparatus of the invention comprising a restriction device 418 designed like pincers having two rigid articulated clamping elements 420 positioned on opposite sides of the esophagus 406 (or stomach). An adjustment device 422 turns the clamping elements 420 toward each other to clamp the esophagus 406 between the clamping elements 420 to thereby decrease the cross-sectional area in the esophagus 406, and turns the clamping elements 420 away from each other to release the esophagus 406 from the clamping elements 420 to thereby increase the cross-sectional area in the esophagus 406.

Figs. 39A, 39B and 39C show an embodiment of the apparatus of the invention comprising a restriction device 424 having three bending members in the form of cylindrical rollers 426, 428 and 430 displaced relative one another in a row along the esophagus 406 (or stomach) and positioned alternately on opposite sides of the esophagus 406. (Alternatively, each roller 426, 428 and 430 may take the shape of an hour-glass.) An adjustment device 432 moves the two outer rollers 426,430 laterally against the esophagus 406 in one direction and the intermediate roller 428 against the esophagus 406 in the opposite direction to bend the esophagus to thereby decrease the cross-sectional area in the esophagus

406, see Fig. 39B. To increase the cross-sectional area in the esophagus 406 the adjustment device 432 moves the rollers 426-430 away from the esophagus 406 to release the latter from the rollers 426-430, see Fig. 39C.

Figs. 40A through 44B schematically illustrates modifications of the above embodiment according to Figs. 39A-39C. Thus, Figs. 40A and 40B show an embodiment similar to that of Figs. 39A-39C except that the bending members are oval and not rotatable. Figs. 41A and 41B show an embodiment similar to that of Figs. 40A and 40B except that the oval bending members are rotatable to release the esophagus (or stomach), see Fig. 41A, and squeeze the esophagus, see Fig. 41B. Figs. 42A and 42B show an embodiment similar to that of Figs. 39A-39C except that the intermediate roller has a changeable diameter to release the esophagus (or stomach), see Fig. 42A, and squeeze the esophagus, see Fig. 42B. Figs. 43A and 43B show an embodiment similar to that of Figs. 37A-37C except that the rigid elements are replaced by two cylindrical rollers positioned on opposite sides of the esophagus. Finally, Figs. 44A and 44B show an embodiment substantially similar to that of Figs. 43A and 43B except that the restriction device is turned 90 to form an S-shaped curvature of the esophagus.

Fig. 45 illustrates how any of the above-described embodiments of the heartburn and reflux disease treatment apparatus of the invention may be implanted in a patient. Thus, an assembly 434 of the apparatus implanted in the patient comprises an adjustable restriction device engaging the esophagus 406 close to the cardia and an adjustment device for adjusting the restriction device. The restriction device of the assembly 434 is provided with a soft support member 435, which abuts upwardly against the diaphragm 437 of the patient. A wireless remote control of the apparatus comprises

an external signal transmitter 436 and an implanted signal receiver 438, which comprises a control unit for controlling the adjustment device of the implanted assembly 434 in response to signals from the transmitter 436. The signal receiver 438 further comprises an energiser unit which transfers energy from the signals transmitted by the transmitter 436 into electric energy for energy consuming implanted components of the device.

There are a number of other conceivable alternative embodiments of the invention that give the same result as the above-described embodiments. For example, the microprocessor of the external and implanted, respectively, control unit may be replaced by discrete components. The power amplifier of the external control unit may be omitted if the signals generated by the signal generator are strong enough. Therefore the invention is to be accorded the broadest interpretation of the appended claims to encompass all equivalent structures and assemblies.

One further advantage with this invention is that there may be a night button on the remote control setting the adjustment device in a position with a larger cross-sectional area of the food passage in the esophagus or stomach during the night, thus avoiding vomiting or nausa. Both the amount of restriction and time schedule are preferably programmed from outside the patient's body. A sensor sensing for example the position of the patient may be used in a feedback regulation system.

CLAIMS

1. A heartburn and reflux disease treatment apparatus, comprising an adjustable restriction device (2;48;60,62;88;110;122;126,128;130) adapted to engage the stomach close to the cardia or esophagus of a patient to form a restricted food passageway in the stomach or esophagus, **characterised** by a post-operation adjustment device (12;52;66;90,92;104;110) designed to mechanically adjust the restriction apparatus to enlarge or restrict the food passageway, when the restriction device is implanted in the patient.

2. An apparatus according to claim 1, wherein the restriction device (2;48;60,62;88;110;122;126,128;130) is adjustable by the adjustment device (12;52;66;90,92;104;110) to enlarge the food passageway when the patient eats and to restrict or close the food passageway between meals, when the restriction device is implanted in the patient.

3. An apparatus according to claim 1 or 2, wherein the adjustment device is operable in a non-invasive manner to adjust the restriction device, when the restriction device is implanted in the patient.

4. An apparatus according to claim 1, wherein the adjustment device (12;52;66;90,92;104;110) is adapted to adjust the restriction device in a non-magnetic or non-thermal manner.

5. An apparatus according to any of claims 1-4, wherein the restriction device is adapted to control the cross-sectional area of the food passageway.

6. An apparatus according to claim 5, wherein the restriction device is operable to open and close the food passageway.

7. An apparatus according to claim 6, wherein the restriction device is adapted to steplessly control the cross-sectional area of the food passageway.

8. An apparatus according to any one of claims 1-7, further comprising a powered operation device for operating the adjustment device.

9. An apparatus according to any one of claims 1-8, wherein the restriction device comprises an element to be placed on one side of the stomach or esophagus, and the adjustment device is adapted to squeeze the stomach or esophagus between the element and the human bone or tissue to restrict the food passageway.

10. An apparatus according to any one of claims 1-8, wherein the restriction device comprises at least one elongated restriction member (2;48;60,62;88) and forming means (10;94;106;108;118;132) for forming the restriction member into at least a substantially closed loop around the stomach or esophagus, the loop defining a restriction opening, whereby the adjustment device is adapted to adjust the restriction member in the loop to change the size of the restriction opening.

11. An apparatus according to claim 10, wherein the restriction device comprises several elongated restriction members (2;48;60,62;88) to be formed into at least substantially closed loops around the stomach or esophagus.

12. An apparatus according to claim 10 or 11, wherein, the adjustment device (12;52;66;90,92) is adapted to adjust the longitudinal extension of the elongated restriction member in said loop to change the size of the restriction opening.

13. An apparatus according to claim 12, wherein the restriction member (2;48) comprises a main portion and two elongated end portions (4,6), and the adjustment device (12;52;66;90,92) is adapted to establish longitudinal relative displacement between the end portions of the restriction member, such that the size of the restriction opening (3) is adjusted.

14. An apparatus according to claim 7, wherein the adjustment device (12;52;66;90,92) comprises a movement transferring member (14;40;78,90;80,92) in engagement with at least one of the end portions (4,6) of the restriction member and operable to displace said one end portion relative to the other end portion of the restriction member.

15. An apparatus according to claim 14, further comprising a motor (22), which is fixed relative to the main portion of the restriction member (2) and has a rotating drive shaft (32) operatively connected to the movement transferring member (14).

16. An apparatus according to claim 15, wherein the motor is positioned relative to the elongated restriction member

such that the drive shaft extends in parallel with a chord in said loop of the restriction member.

17. An apparatus according to claim 12, wherein the elongated restriction member (48,50) is longitudinally resilient and the adjustment device comprises a contraction means (52) adapted to longitudinally contract the resilient restriction member.

18. An apparatus according to claim 17, wherein the elongated restriction member comprises a substantially nonresilient main portion (48) and an end portion forming an elongated helical spring (50), which is contractable by the contraction means (52).

19. An apparatus according to claim 18, wherein the contraction means comprises an elongated flexible pulling member (52) connected to the main portion (48) of the restriction member and extending through the helical spring (50) to contract the helical spring against an arresting member (56), which is fixed relative to the main portion of the restriction member.

20. An apparatus according to claim 10, wherein the restriction member comprises an elongated helical spring (60) having a free end, and a body (64) to which said spring is nonrotatably secured at its opposite end, the adjustment device (66) being adapted to rotate the helical spring in one direction to enlarge the coils of the helical spring to longitudinally contract the elongated helical spring and to rotate the helical spring in the opposite direction to reduce the size of the coils of the helical spring to longitudinally extend the helical spring.

21. An apparatus according to claim 20, wherein the restriction member comprises a further elongated helical spring (62) having a free end and nonrotatably secured to the body (64) at its opposite end, and the adjustment device comprises a drive shaft (66) having two opposite end portions connected to the helical springs, respectively, at their free ends, the helical coils forming left and right hand helices, respectively.

22. An apparatus according to claim 21, wherein the restriction member comprises a further elongated helical spring (62) having a free end and nonrotatably secured to the body (64) at its opposite end, and the adjustment device comprises a gearing (70) having an input shaft (78) and two opposite aligned output shafts (74,76) connected to the helical springs (60,62), respectively, at their free ends, the input shaft being connected to the output shafts such that the output shafts rotate in the opposite directions upon rotation of the input shaft, the helical coils forming the same helices.

23. An apparatus according to claim 10, wherein the restriction member (88;110;122) forms a radially innermost circumferential confinement surface in said loop of the restriction member, and the adjustment device (104;112) is adapted to mechanically adjust the restriction member such that at least a portion of the confinement surface is substantially radially displaced in said loop.

24. An apparatus according to claim 23, wherein the adjustment device comprises an elongated voltage responsive element (104) forming part of the confinement surface and

capable of bending into a bow in response to a voltage applied across the element, the radius of curvature of said bow being adjustable by changing the level of the voltage.

25. An apparatus according to claim 23, wherein the restriction member comprises an elastic annular element (110) forming the confinement surface, and the adjustment device (112) is adapted to change the diameter of the elastic annular element.

26. An apparatus according to claim 23, wherein the forming means comprises a substantially rigid outer annular element (118), and the restriction member comprises an elongated helical spring (60) extending internally along the outer annular element and contacting the latter, the helical spring forming part of the circumferential confinement surface and having a free end, and a body to which the helical spring is nonrotatably secured at its opposite end, the adjustment device being adapted to rotate the helical spring in one direction to enlarge the coils of the helical spring to contract the circumferential confinement surface and to rotate the helical spring in the opposite direction to reduce the size of the coils of the helical spring to expand the circumferential confinement surface.

27. An apparatus according to claim 23, wherein the forming means comprises a substantially rigid outer annular element (118), and the restriction member comprises a first (60) and a second (62) elongated helical spring extending internally along the outer annular element and contacting the latter, the helical springs forming part of the circumferential confinement surface, the first and the second spring, respectively, having a free end, and a body to which

the first and the second spring, respectively, is nonrotatably secured at its opposite end, the adjustment device being adapted to rotate the first and the second spring, respectively, in one direction to enlarge the coils of the spring to contract the circumferential confinement surface and to rotate the first and the second spring, respectively, in the opposite direction to reduce the size of the coils of the spring to expand the circumferential confinement surface.

28. An apparatus according to claim 10, wherein the restriction member comprises at least two separate elements, at least one of which is pivoted such that it is turnable in a plane in which said loop of the restriction member extends, and the adjustment device is adapted to turn said pivoted element to change the size of said restriction opening.

29. An apparatus according to any one of claims 1-8, wherein the restriction device comprises at least two frame elements (126 and 128), which are foldable towards each other by the adjustment device.

30. An apparatus according to claim 29, wherein the foldable frame elements comprise two substantially semi-circular frame elements (126 and 128), which are hinged together such that the semicircular elements are swingable relative to each other from a fully open state in which they substantially form a circle to a fully folded state in which they form a semicircle.

31. An apparatus according to claim 10, wherein the elongated restriction member (130) is elastic and varies in thickness as seen in a cross-section therethrough, and the

adjustment device is adapted to turn the restriction member around the longitudinal extension thereof.

32. An apparatus according to claim 10, wherein the forming means comprises a spring material forming the elongated restriction member into the loop, such that the restriction opening has a predetermined size, and the adjustment device is adapted to adjust the restriction member against the spring action of the spring material.

33. An apparatus according to claim 32, wherein the spring material is integrated in the restriction member.

34. An apparatus according to claim 10, wherein the forming means (10;94;106;108;118;132) is adapted to form the restriction member (2;48;60,62;88;110;122;126,128;130) into a loop having a predetermined size or a size selected from several predetermined sizes.

35. An apparatus according to claim 10, wherein the adjustment device (12;52;66;90;104;110) is adapted to change the size of the restriction opening (3) such that the outer circumferential confinement surface of the restriction member (2;48;60,62;88;110;122;126,128;130) is changed.

36. An apparatus according to claim 10, wherein the adjustment device (12;52;66;90;104;110;434) is adapted to change the size of the restriction opening (3) such that the outer circumferential confinement surface of the restriction member (2;48;60,62;88;110;122;126,128;130:436) is unchanged.

37. An apparatus according to claim 10, wherein the elongated restriction member (404) is flexible, and the

adjustment device (410) is adapted to pull a first portion (404A) of the flexible restriction member from a second portion (404B) of the flexible restriction member opposite the first portion in the loop to squeeze the stomach or esophagus (406) between two opposite lengths of the elongated flexible restriction member to restrict the food passageway in the stomach or esophagus (406), and to release the stomach or esophagus (406) from the flexible restriction member to enlarge the food passageway (Figs. 36A,36B).

38. An apparatus according to any one of claims 1-8, wherein the restriction device (412) comprises at least two elements (414) to be placed on different sides of the stomach or esophagus (406), and the adjustment device is adapted to squeeze the stomach or esophagus (406) between the elements to restrict the food passageway in the stomach or esophagus (406), and to release the stomach or esophagus (406) from the elements to enlarge the food passageway (Figs. 37A,37B).

39. An apparatus according to any one of claims 1-8 wherein the restriction device (418) comprises at least two articulated clamping elements (420) to be positioned on opposite or different sides of said portion of the stomach or esophagus (406), and the adjustment device (422) is adapted to turn the clamping elements toward each other to clamp the stomach or esophagus (406) between the clamping elements to restrict the food passageway in the stomach or esophagus (406), and to turn the clamping elements away from each other to release said portion of the stomach or esophagus (406) from the clamping elements to enlarge the food passageway (Fig. 38).

SDOCID: <WO__0149245A2_I_>

40. An apparatus according to any one of claims 1-8, wherein the restriction device is adapted to bend a portion of the stomach or esophagus (406) (Figs. 39A-44B).

41. An apparatus according to claim 40, wherein the restriction device (424) comprises at least two bending members (426-430) to be positioned on opposite or different sides of the stomach or esophagus (406) and to be displaced relative to each other along the food passageway in said portion of the stomach or esophagus (406), and the adjustment device (432) is adapted to move the bending members against said portion of the stomach or esophagus (406) to bend it to restrict the food passageway, and to move the bending members away from said portion of the stomach or esophagus (406) to release it from the bending members to enlarge the food passageway (Figs. 39A-39C).

42. An apparatus according to claim 41, wherein the bending members comprise rollers.

43. An apparatus according to any one of claims 1-8, wherein the restriction device is adapted to rotate a portion of the stomach or esophagus.

44. An apparatus according to claim 8, wherein the operation device comprises a motor (22;68;124;130;136) operatively connected to the adjustment device (12;52;66;90,92;104;110).

45. An apparatus according to claim 44, wherein the operation device comprises a reverse servo connected between the motor and the adjustment device.

46. An apparatus according to claim 44 or 45, comprising an implantable reversing device for reversing the motor.

47. An apparatus according to any of claims 44-46, wherein the motor (22;68;124;130;136) is fixed to the restriction device.

48. An apparatus according to any of claims 44-46, wherein the motor (22) is remote from the restriction member (2) and is connected to the adjustment device (14) by a power transmission conduit (24).

49. An apparatus according to claim 8, wherein the operation device comprises a servo means.

50. An apparatus according to claim 49, wherein the servo means comprises a motor, preferably an electric motor.

51. An apparatus according to claim 50, wherein the motor is reversible.

52. An apparatus according to claim 8, wherein the operation device comprises hydraulic means (54) for operating the adjustment device (52).

53. An apparatus according to claim 52, further comprising a reservoir (204;210;216) containing a predetermined amount of fluid for supplying the hydraulic means with fluid.

54. An apparatus according to claim 53, wherein the reservoir (210) defines a chamber for the predetermined amount of fluid and the hydraulic means (202) is adapted to change the volume of the chamber.

55. An apparatus according to claim 53 or 54, wherein the hydraulic means comprises a pump (212) adapted to pump fluid between the reservoir (204) and the adjustment device (202).

56. An apparatus according to any of claims 52-55, wherein the hydraulic means is devoid of any non-return valve.

57. An apparatus according to any one of claims 53-56, wherein the hydraulic means comprises a reverse servo (210,214;276-286).

58. An apparatus according to claim 57, wherein the reverse servo is manually operated.

59. An apparatus according to claim 57, wherein the reverse servo is powered.

60. An apparatus according to any of claims 57-59, wherein the hydraulic means comprises first and second wall portions of the reservoir (204), and the reverse servo is adapted to provide relative displacement between the first and second wall portions of the reservoir.

61. An apparatus according to any one of the preceding claims, further comprising a wireless remote control (22,326,332-344) for non-invasively controlling the adjustment device.

62. An apparatus according to claim 61, wherein the remote control (22,326,332-344) comprises a separate signal transmitter and/or receiver (332,336) and an implantable signal receiver and/or transmitter (334,338), for transmitting and/or receiving a control signal.

63. An apparatus according to claim 62, wherein the signal receiver (334,338) comprises a control unit (338) adapted to control the adjustment device (12;52;66;90,92;104;110) in response to the control signal.

64. An apparatus according to claim 63, further comprising an implantable energiser unit (336) for providing energy to energy consuming components of the apparatus to be implanted in the patient.

65. An apparatus according to any of claims 61-64, further comprising an implantable motor (22) for operating the adjustment device (12;52;66;90,92;104;110).

66. An apparatus according to claims 64 and 65, wherein the control unit (338) is adapted to control the energiser unit (336) to power the motor (22) with energy in response to the control signal.

67. An apparatus according to claim 65 or 66, wherein the motor (22) is an electric motor.

68. An apparatus according to claim 64, wherein the energiser unit (326) is adapted to transform energy from the control signal, as it is transmitted to the signal receiver (334,338), into electric energy.

69. An apparatus according to claim 64 or 68, wherein the energiser unit (26) is adapted to transform energy from the control signal into a direct or alternating current.

70. An apparatus according to claim 68, further comprising an implantable electric motor (22) for operating

the adjustment device (12;52;66;90,92;104;110), wherein the energiser unit (326) comprises a rechargeable electric power supply (58) for storing the electric energy and the control unit (338) is adapted to power the electric motor (22) with energy from the rechargeable electric power supply in response to the control signal.

71. An apparatus according to claim 64, wherein the energiser unit (326) comprises a battery, an electrically operable switch adapted to connect the battery to the signal receiver in (334,338) an "on" mode when the switch is powered and to keep the battery disconnected from the signal receiver in a "standby" mode when the switch is not powered, and a rechargeable electric power supply for powering the switch.

72. An apparatus according to claim 71, wherein the control unit (338) is adapted to power the electric motor (22) with energy from the battery in response to a control signal received from the signal transmitter (332,336), when the switch is in its "on" mode.

73. An apparatus according to claim 64, further comprising an external energy transmitter for transmitting wireless energy, wherein the energiser unit comprises a battery and a switch operable by the wireless energy transmitted by the external transmitter, for connecting the battery to the signal receiver in an "on" mode when the switch is powered by the wireless energy and to keep the battery disconnected from the signal receiver in a "standby" mode when the switch is not powered.

74. An apparatus according to claim 1, further comprising an implantable energiser unit (336) for providing energy to

energy consuming components of the apparatus to be implanted in the patient.

75. An apparatus according to claim 74, further comprising an external energy transmitter for transmitting wireless energy, wherein the energiser unit is adapted to transform the wireless energy into electric energy.

76. An apparatus according to claim 75, further comprising an implantable electric motor (22) for operating the adjustment device (12;52;66;90,92;104;110), wherein the energiser unit (326) is adapted to power the electric motor (22) with the electric energy transformed from the wireless energy.

77. An apparatus according to claim 74, further comprising an external energy transmitter for transmitting wireless energy, wherein the energiser unit comprises a battery and a switch operable by the wireless energy transmitted by the external transmitter, for connecting the battery to the implantable energy consuming components of the apparatus in an "on" mode when the switch is powered by the wireless energy and to keep the battery disconnected from the energy consuming components in a "standby" mode when the switch is not powered.

78. An apparatus according to claim 73 or 76, wherein the external energy transmitter is adapted to directly power the switch with the wireless energy to switch into the "on" mode.

79. An apparatus according to claim 61, wherein the remote control (22,326,332-344) is capable of obtaining information from implantable components of the apparatus and of commanding the adjustment device (12;52;66;90;104;110) to

adjust the restriction device (2;48;60,62;88;110;122;126,128;130;434) in response to obtained information.

80. An apparatus according to claim 1, further comprising implantable electrical components including at least one voltage level guard.

81. An apparatus according to claim 1, further comprising implantable electrical components including a single voltage level guard.

82. An apparatus according to claim 80 or 81, wherein the electrical components are devoid of any current detector and/or charge level detector.

83. An apparatus according to any of claims 80-82, further comprising an implantable capacitor or accumulator, wherein the charge or discharge of the capacitor or accumulator is controlled by use of the voltage level guard.

84. An apparatus according to claim 1, further comprising an energy transfer means (22,326,332-344) for wireless transfer of energy from outside the patient's body to the adjustment device and/or other energy consuming implantable components of the apparatus.

85. An apparatus according to claim 84, wherein the energy transfer means is adapted to intermittently transfer the energy in the form of a train of energy pulses for direct use in connection with the energising of the energy consuming components of the apparatus.

;DOCID: <WO__0149245A2_I_>

86. An apparatus according to claim 85, wherein the energy transfer means is adapted to transfer electric energy, and further comprising an implantable capacitor for producing the train of energy pulses.

87. An apparatus according to claim 83 or 86, wherein the capacitor has a capacity less than 0,1 μF.

88. An apparatus according to claim 84, further comprising an implantable motor (22) or pump for operating the adjustment device (12;52;66;90,92;104;110), wherein the energy transfer means is adapted to directly power the motor or pump with transferred energy.

89. An apparatus according to claim 1, further comprising an implantable motor or pump for operating the adjustment device, wherein the energy transmission device is adapted to transmit wireless energy in the form of an magnetic field or electromagnetic waves for direct power of the motor or pump, as the wireless energy is being transmitted.

90. An apparatus according to claim 89, wherein the pump is not a plunger type of pump.

91. An apparatus according to claim 84, wherein the energy transfer means is adapted to transfer wireless energy in the form of electromagnetic waves excluding radio waves.

92. An apparatus according to claims 84 or 85, wherein the energy transferred by the energy transfer means comprises an electric field or a magnetic field.

ISDOCID: <WO___0149245A2_I_>

93. An apparatus according to claims 84 or 85, wherein the energy transferred by the energy transfer means comprises a signal.

94. An apparatus according to claim 62 or 93, wherein the signal comprises analog or digital pulses.

95. An apparatus according to claim 94, wherein the analog or digital pulses comprise a magnetic field or an electric field.

96. An apparatus according to claim 62,92 or 93, wherein the signal comprises a wave signal.

97. An apparatus according to claim 96, wherein the wave signal comprises an electromagnetic wave signal, a sound wave signal or a carrier wave signal.

98. An apparatus according to any one of the preceding claims, further comprising a pressure sensor for directly or indirectly sensing the pressure against the restriction device.

99. An apparatus according to claim 98, wherein the restriction device is controlled in response to signals from the pressure sensor.

100. An apparatus according to claim 1, further comprising an implantable energy transforming device for transforming wireless energy directly or indirectly into energy different than the wireless energy for operation of the restriction device.

101. An apparatus according to claim 100, wherein the energy transforming device transforms the wireless energy into kinetic energy for operation of the restriction device.

102. An apparatus according to claim 100, wherein the energy transforming device transforms the wireless energy in the form of sound waves into electric energy for operation of the restriction device.

103. An apparatus according to any one of the preceding claims, further comprising an implantable reversing device, wherein the restriction device is capable of performing a reversible function and the reversing device reverses the reversible function.

104. An apparatus according to any one of the preceding claims, further comprising an implantable accumulator or battery and means for controlling the accumulator or battery from outside the patient's body to supply energy to the adjustment device and/or other implantable energy consuming components of the apparatus.

105. An apparatus according to claim 1, wherein the adjustment device is adapted to adjust the restriction device in a non-manual manner.

106. An apparatus according to claim claim 1 or 2, wherein the adjustment device is powered.

107. An apparatus according to any of claims 52-60, further comprising an injection port subcutaneously implantable in the patient and in fluid communication with the hydraulic means for adding hydraulic fluid to and withdrawing

hydraulic fluid from the hydraulic means (54), for calibrating the amount of hydraulic fluid in the hydraulic means.

108. An apparatus according to claim 1, wherein the restriction device is non-inflatable.

109. An apparatus according to claim 1, further comprising an adjustment device for adjusting the restriction device to change the restriction of the food passageway, wherein the adjustment device is adapted to mechanically adjust the restriction device, or adapted to hydraulically adjust the restriction device by using hydraulic means which is devoid of hydraulic fluid of the kind having a viscosity that substantially increases when exposed to heat or a magnetic field.

110. An apparatus according to claim 102, wherein the energy transforming device transforms the wireless energy in the form of sound waves directly into electric energy.

111. An apparatus according to claim 102,110 or 84, wherein the energy transforming device comprises a capacitor.

112. An apparatus according to claim 111, wherein the capacitor is adapted to produce electric pulses from the transformed electric energy.

113. An apparatus according to claim 59, wherein the reverse servo comprises a motor, preferably an electric motor.

114. An apparatus according to claim 113, wherein the motor is reversible.

115. An apparatus according to claim 97, wherein the carrier signal is frequency, amplitude or frequency and amplitude modulated.

116. An apparatus according to claim 97, wherein the control signal comprises a wave signal comprising one of a sound wave signal including an ultrasound wave signal, an electromagnetic wave signal including an infrared light signal, a visible light signal, an ultra violet light signal and a laser light signal, a micro wave signal, a radio wave signal, an x-ray radiation signal, and a gamma radiation signal.

117. An apparatus according to claim 53, wherein the hydraulic means of the operation device comprises a fluid conduit, the reservoir forming part of the conduit.

118. An apparatus according to claim 117, wherein the hydraulic means including the conduit are devoid of any non-return valve.

119. An apparatus according to claim 84, wherein the energy transfer means is adapted to transfer magnetic energy, non-magnetic energy, electromagnetic energy, non-electromagnetic energy, kinetic energy, non-kinetic energy, sonic energy, non-sonic energy, thermal energy or non-thermal energy.

120. An apparatus according to any one of claims 1-51, wherein the restriction device is non-inflatable.

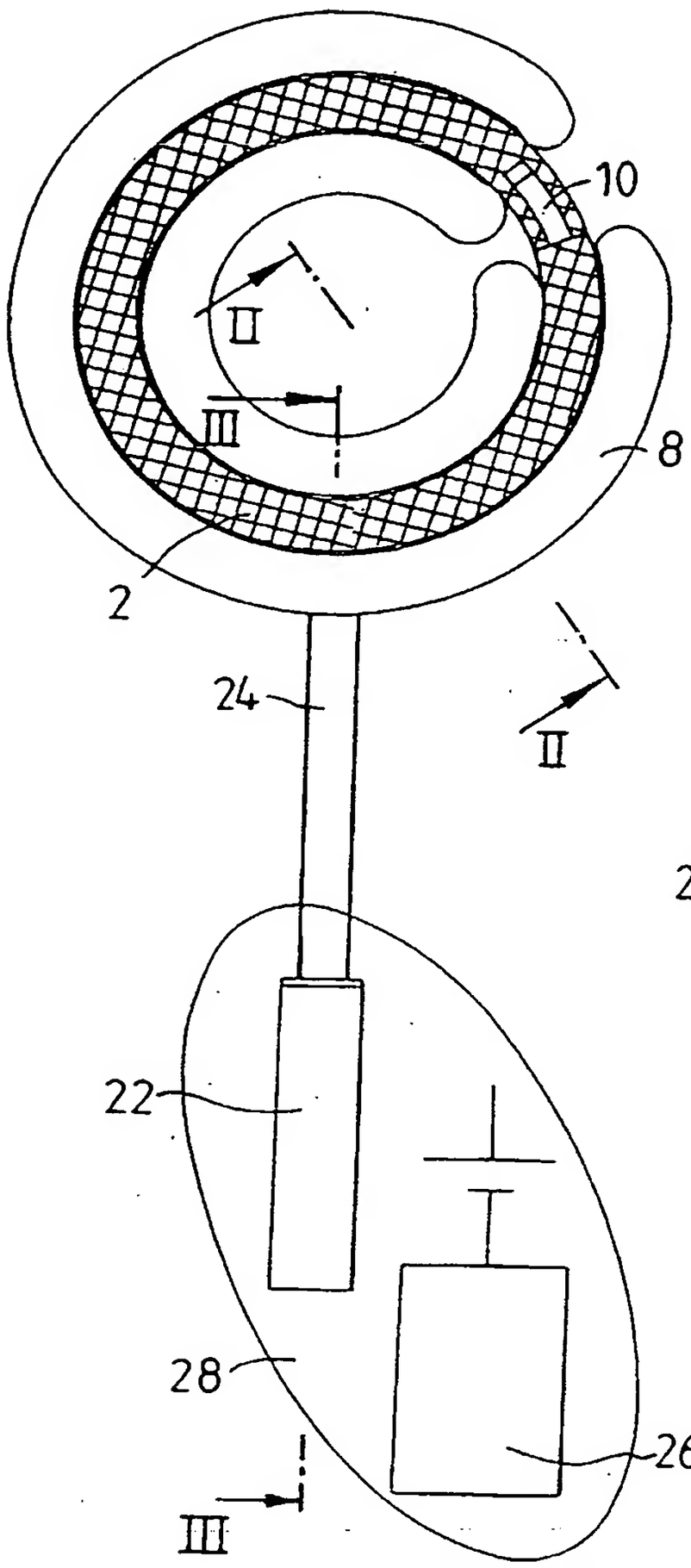


FIG.1

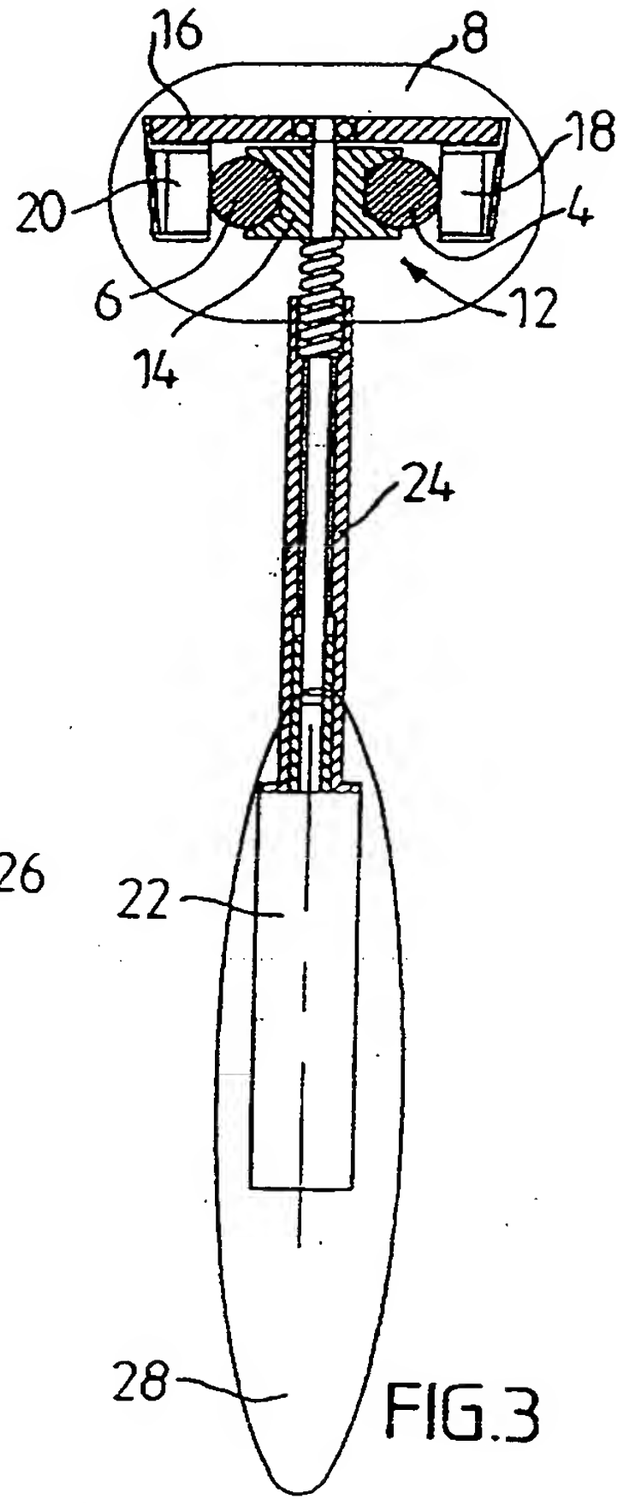


FIG.3

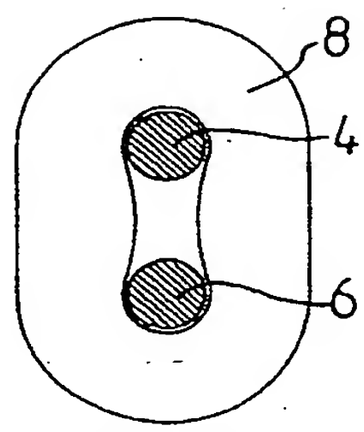


FIG.2

SDOCID: <WO___0149245A2_I_>

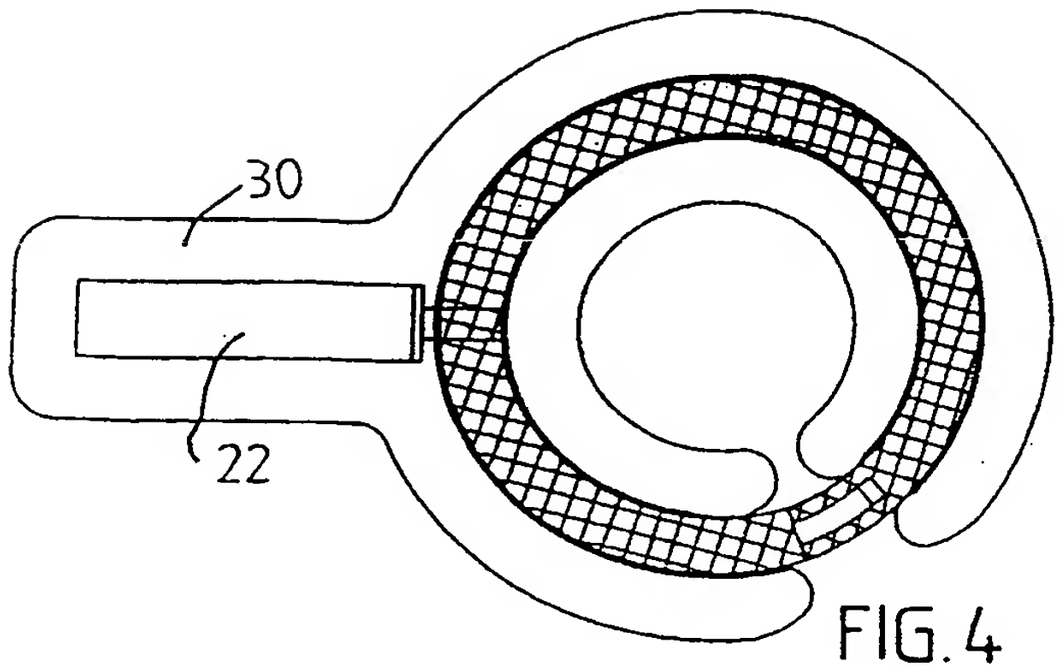


FIG. 4

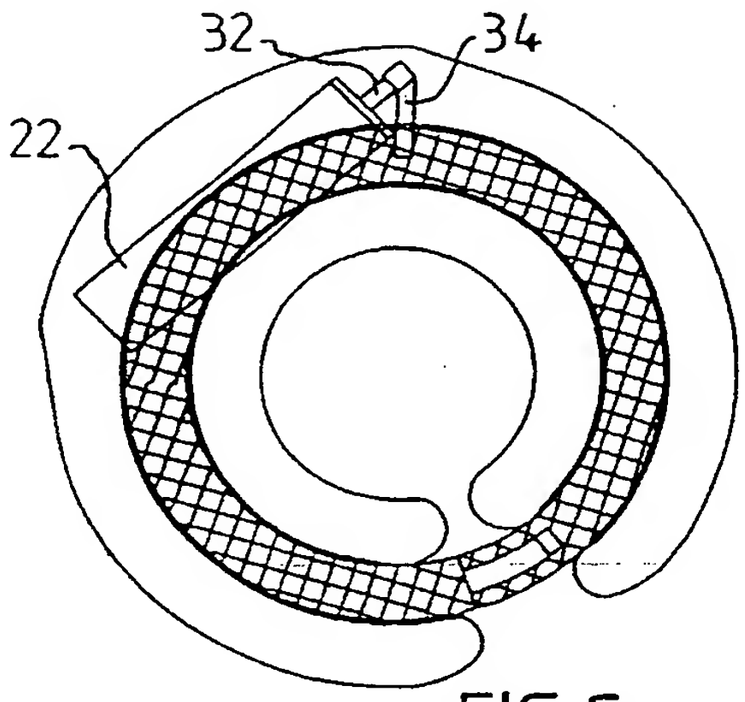


FIG. 5

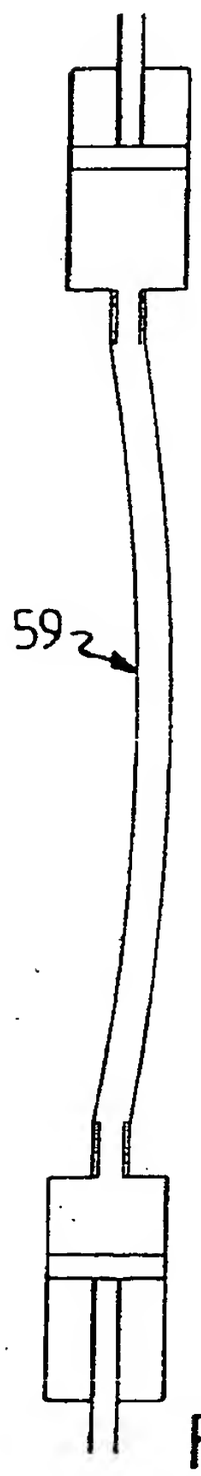


FIG. 8

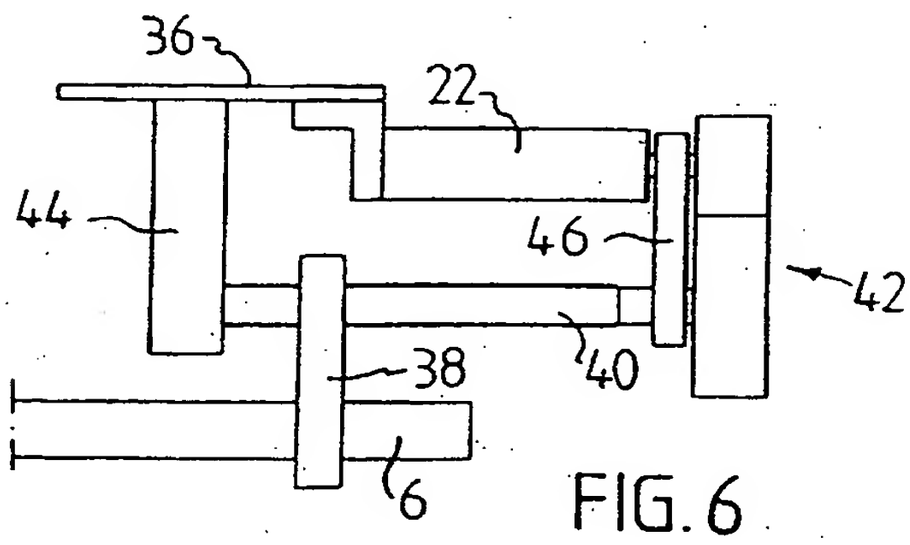


FIG. 6

ISDOCID: <WO___0149245A2_I_>

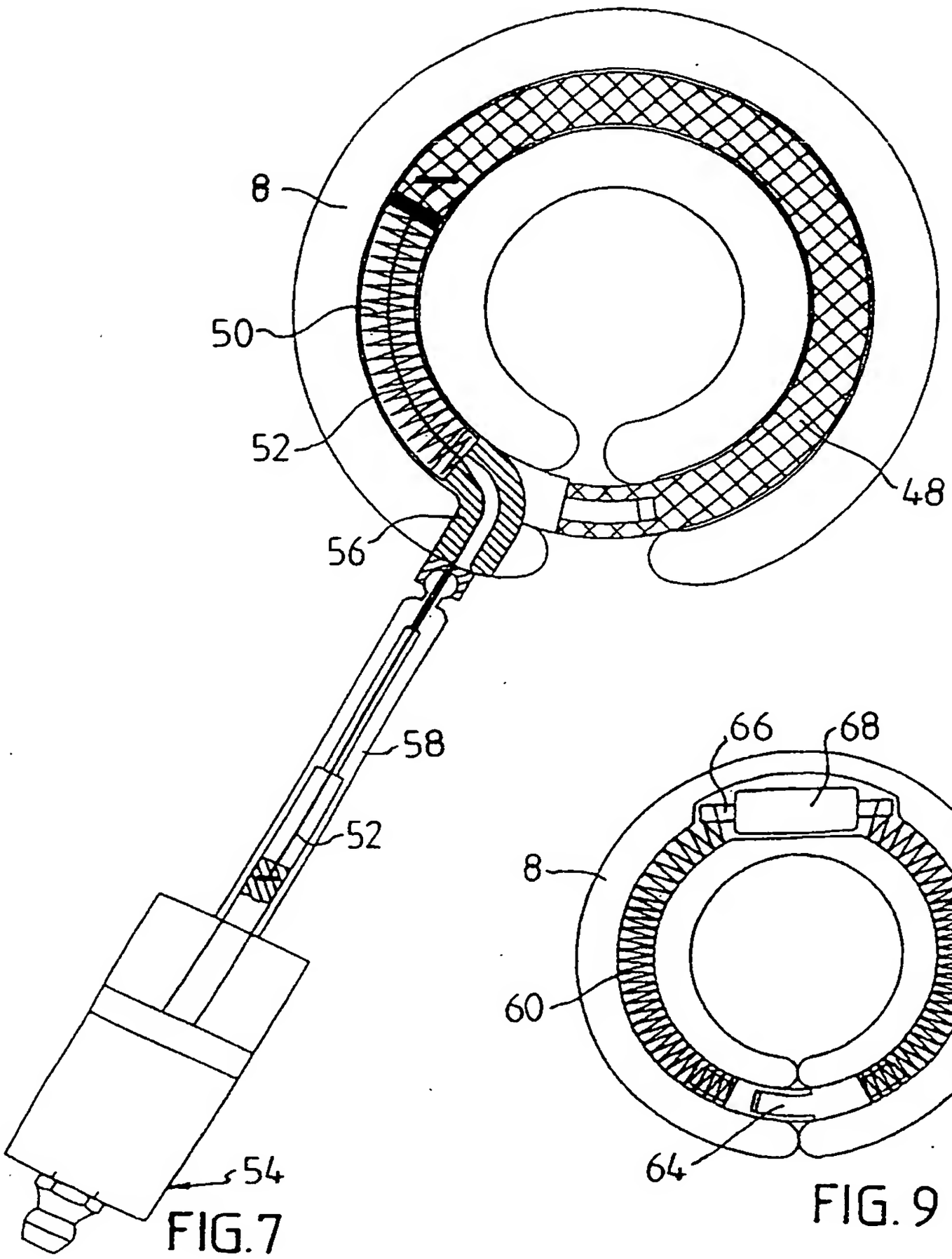


FIG.7

FIG. 9

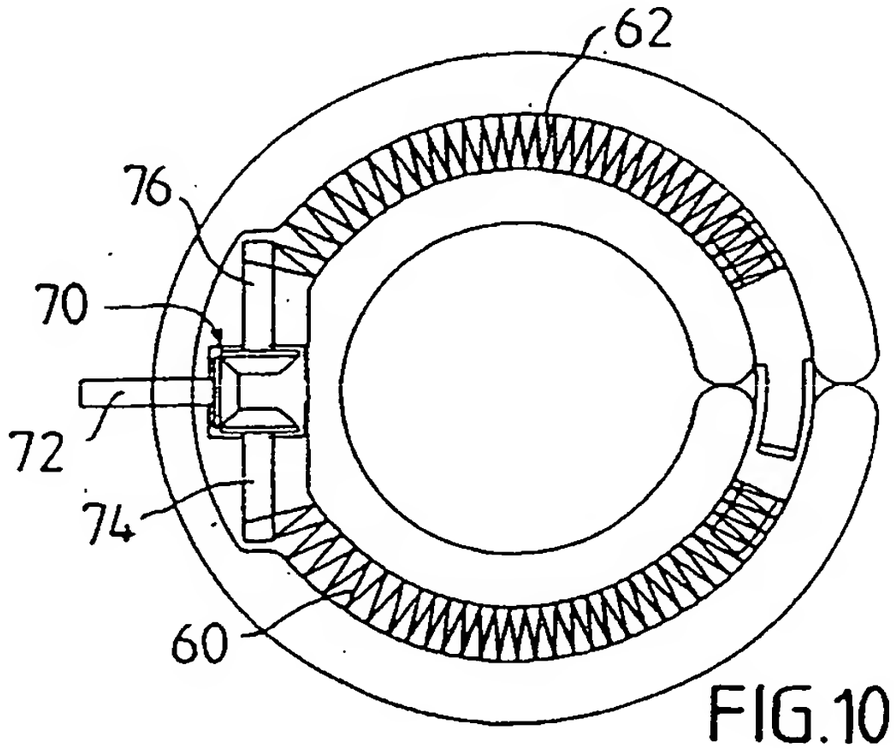


FIG.10

DOCID: <WO___0149245A2_I_>

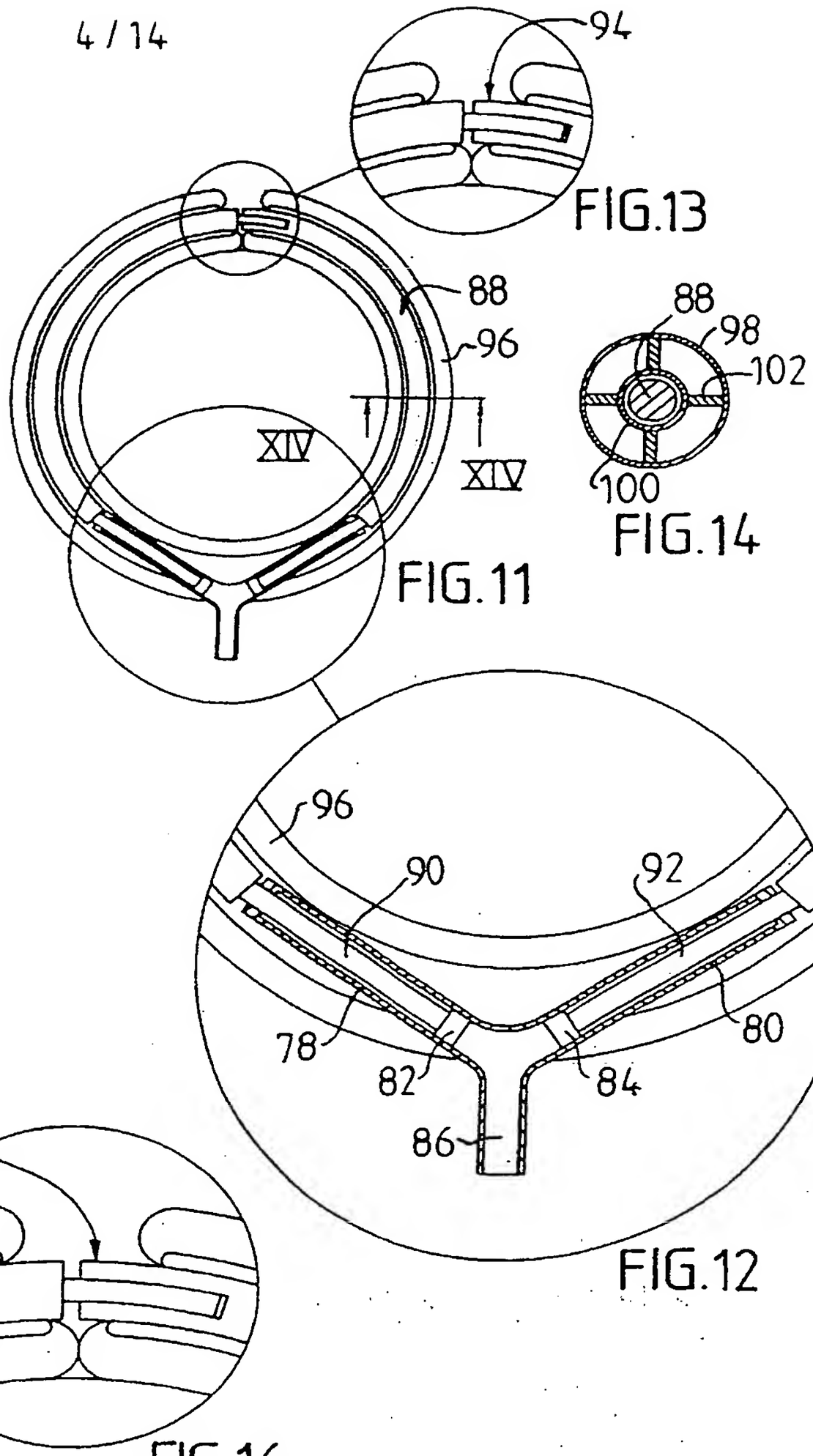


FIG.13

FIG.14

FIG.11

FIG.12

FIG.16

FIG.17

FIG.15

SDOCID: <WO___0149245A2_I_>

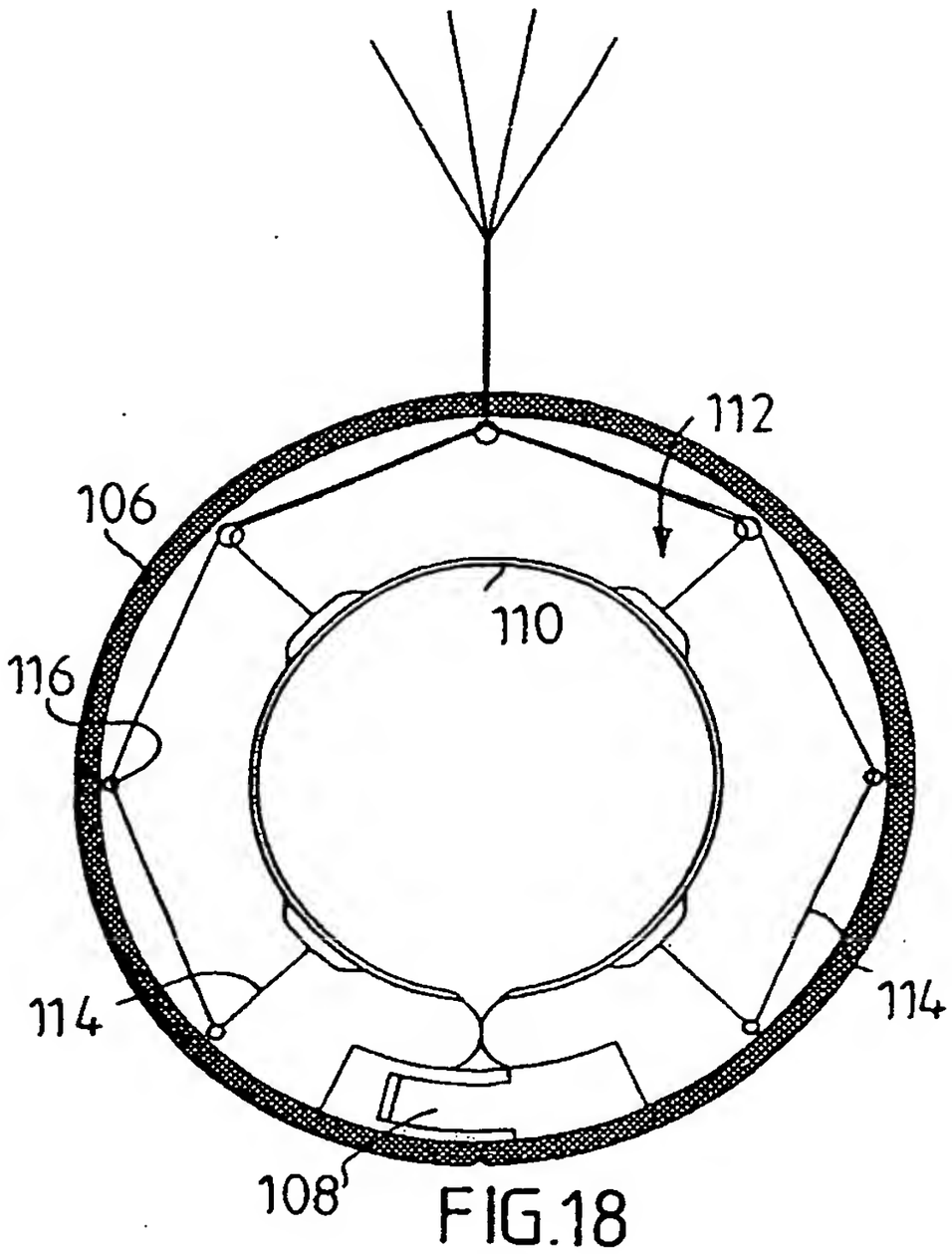


FIG.18

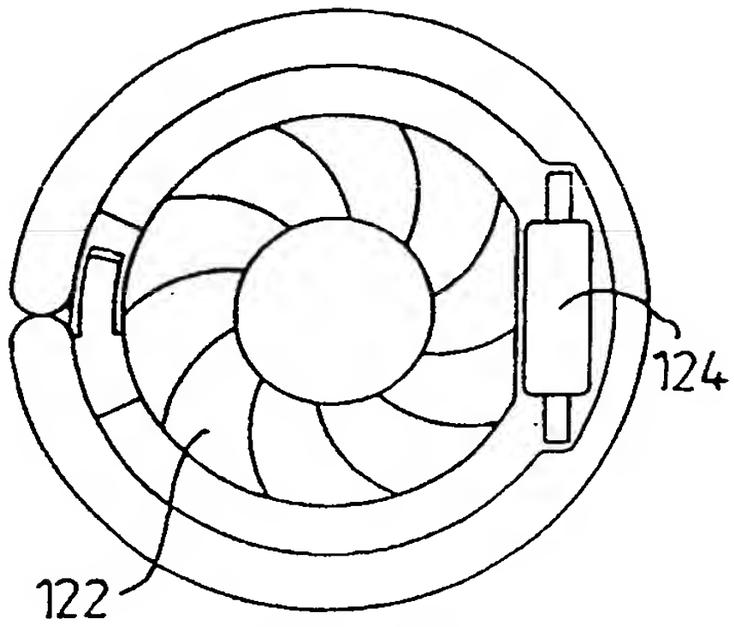


FIG. 20

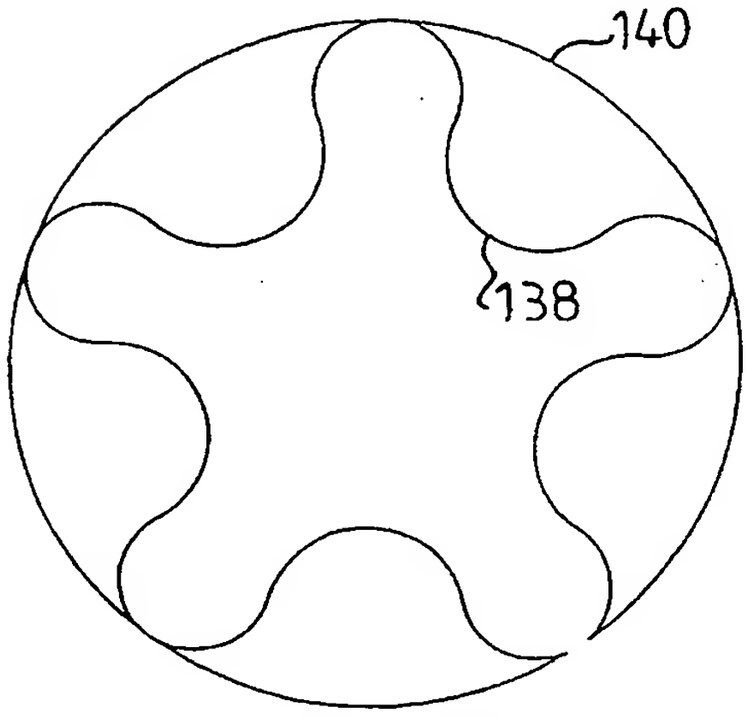


FIG. 28

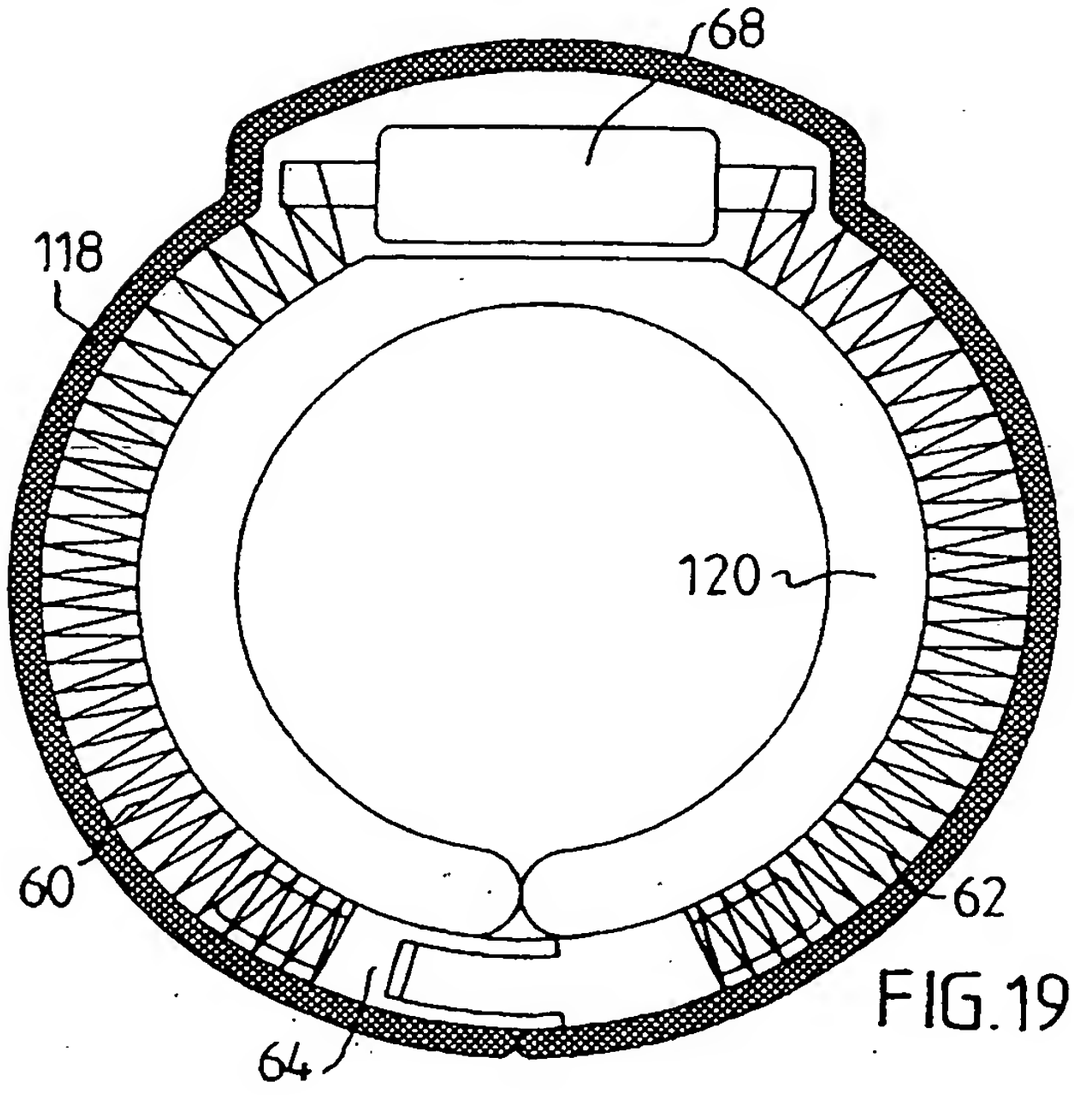


FIG.19

DOCID: <WO___0149245A2_I_>

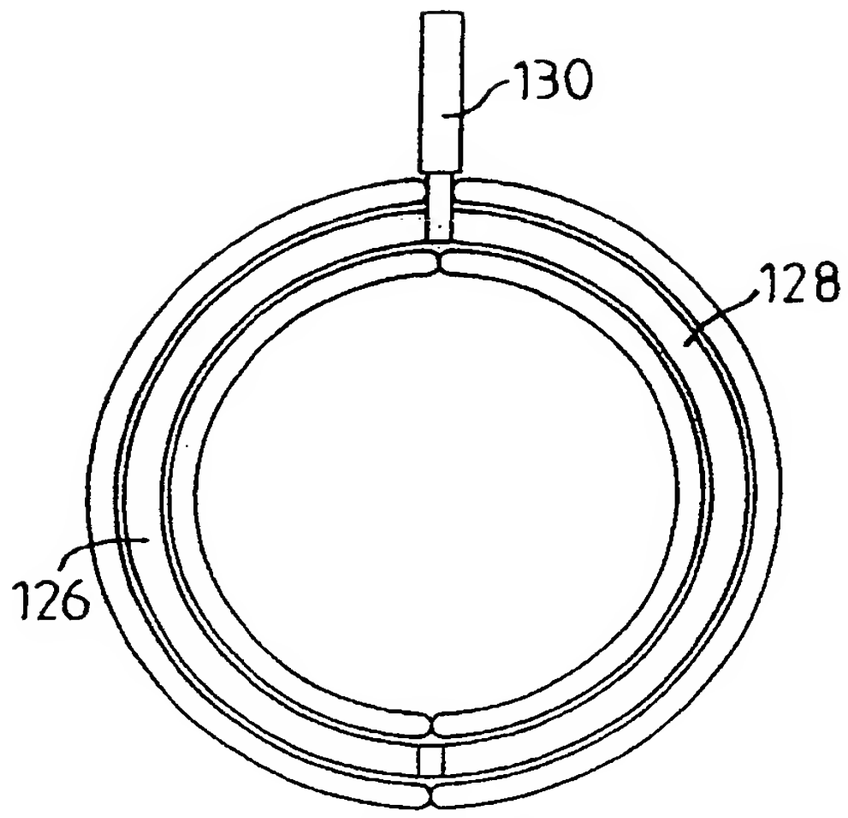
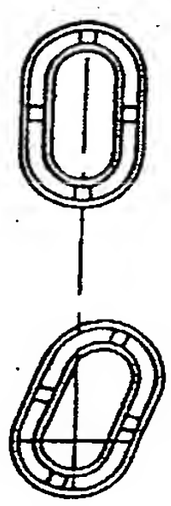


FIG. 21

FIG. 22

FIG. 23



A-A

A-A

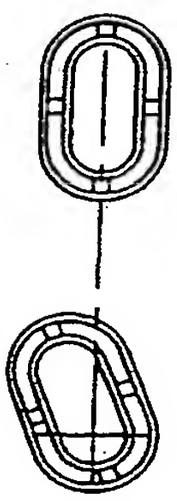


FIG. 26

FIG. 27

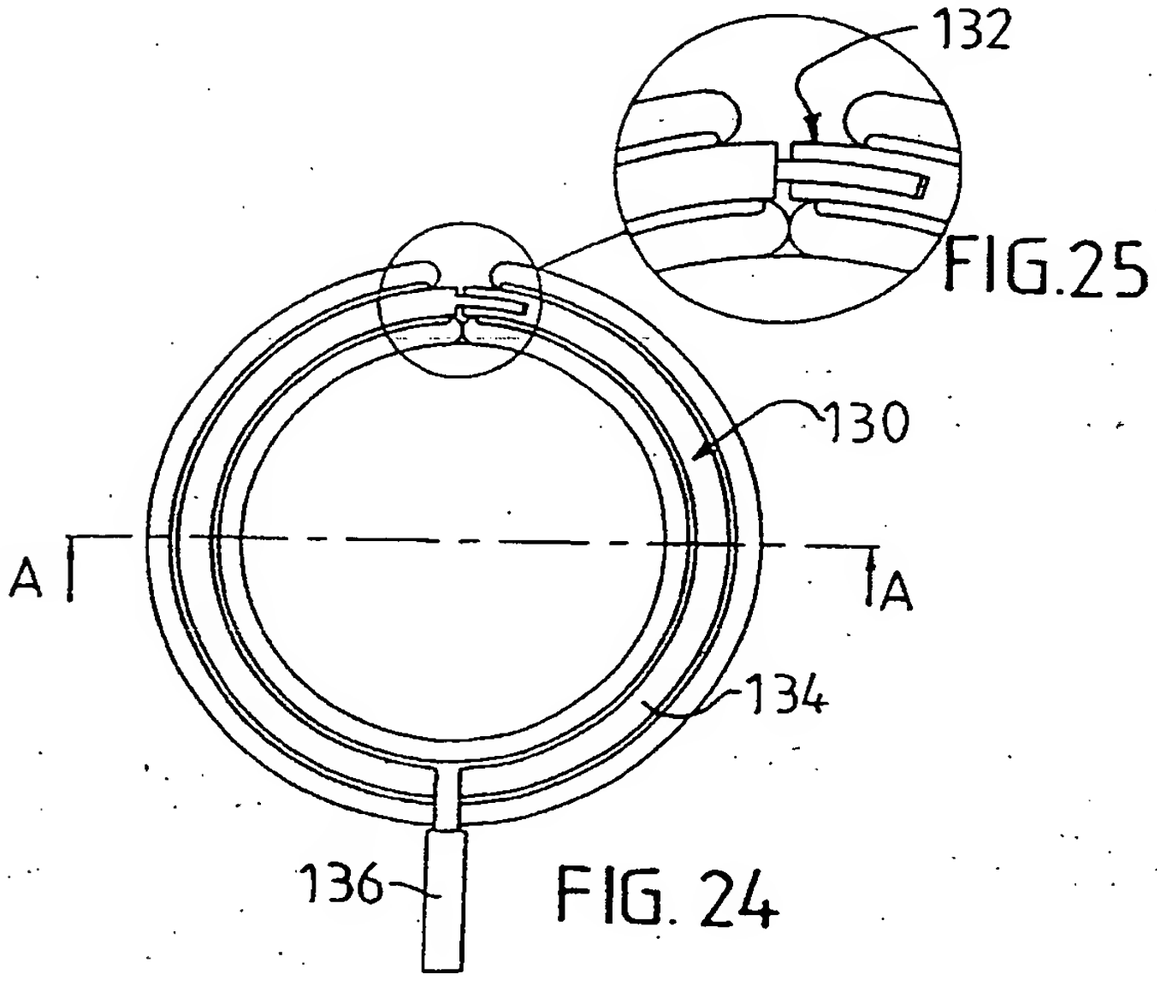


FIG. 25

FIG. 24

ISDOCID: <WO___0149245A2_I_>

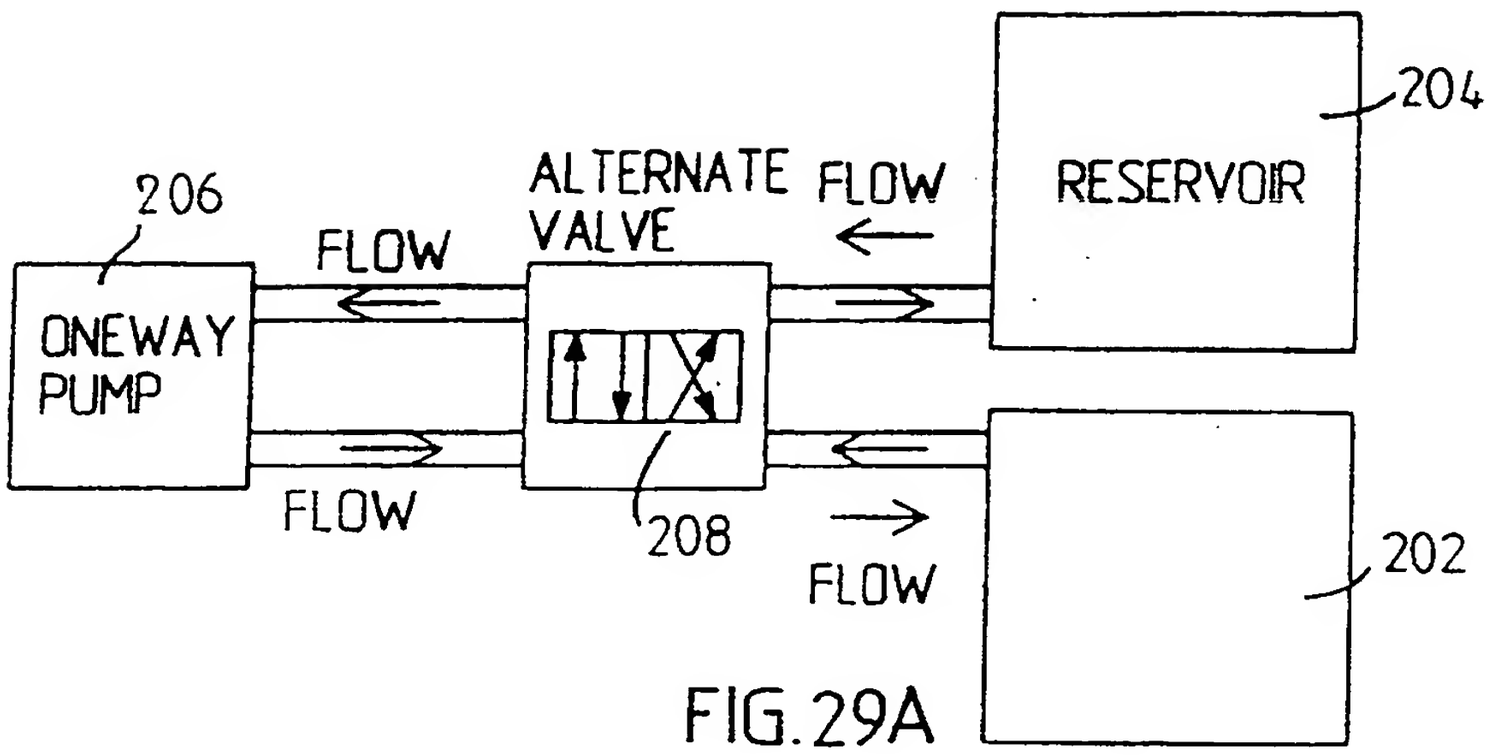


FIG. 29A

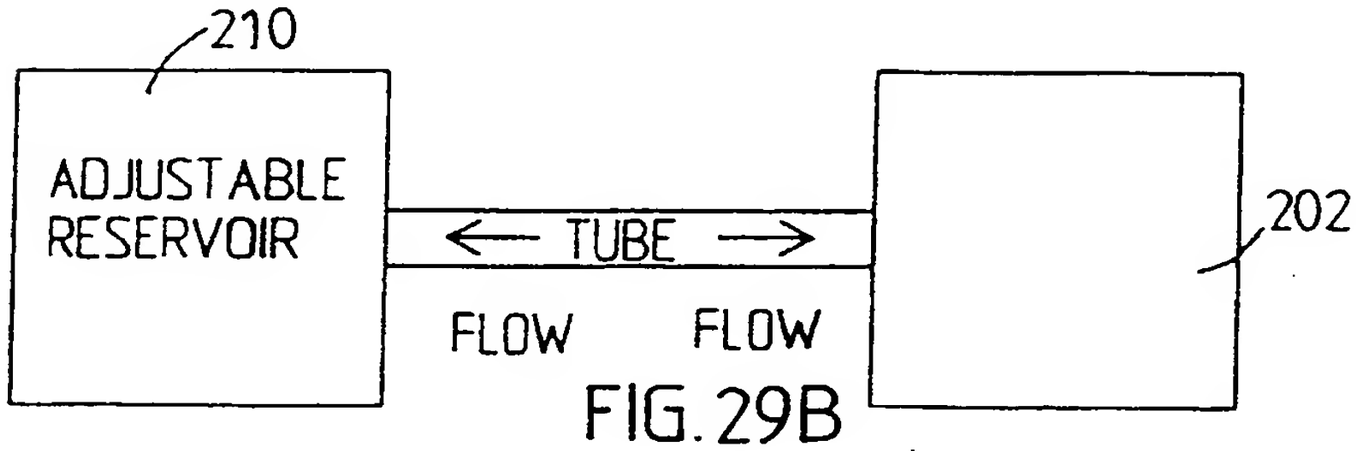


FIG. 29B

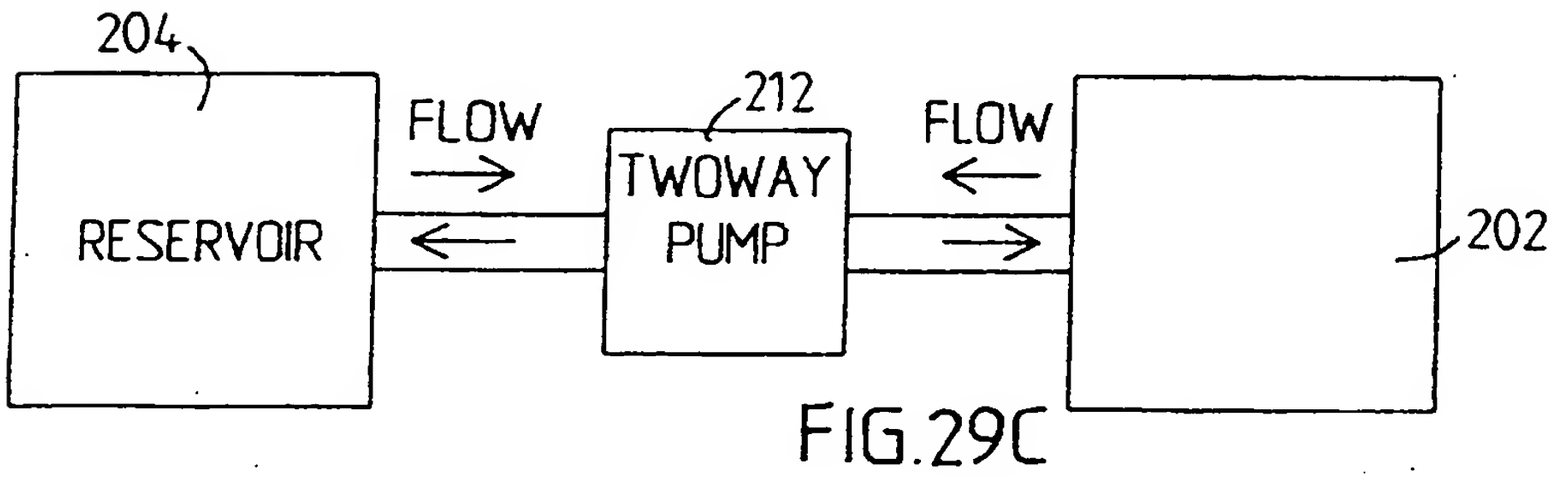


FIG. 29C

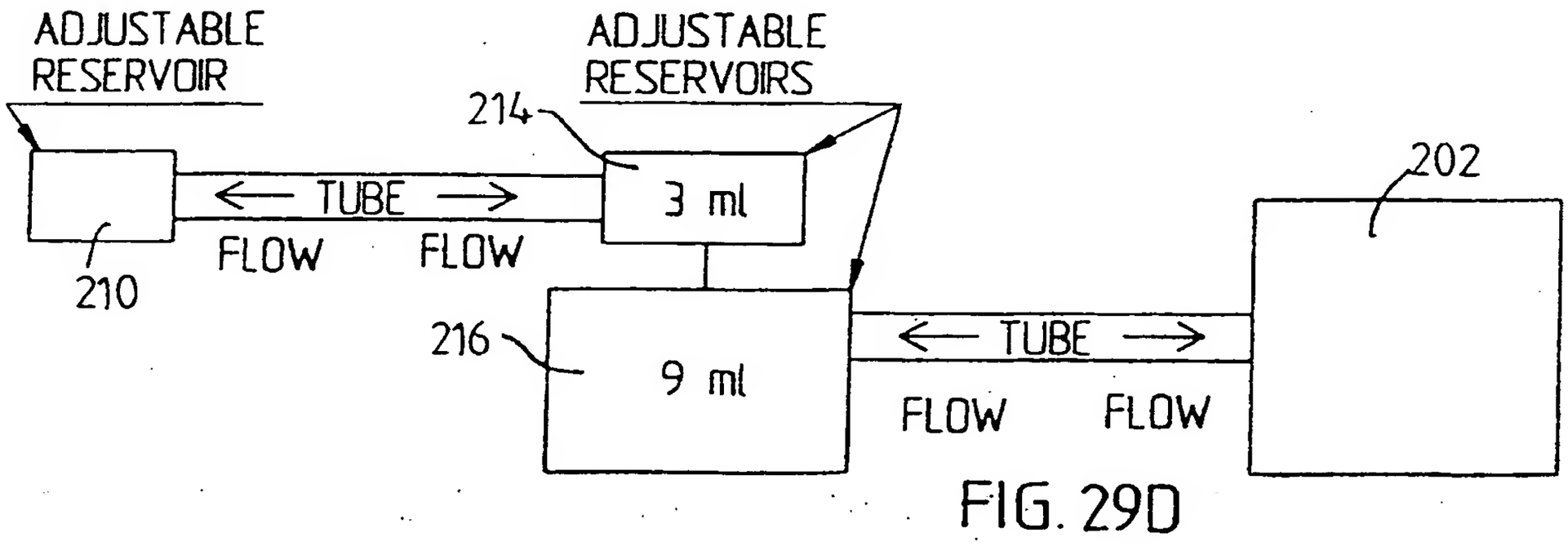


FIG. 29D

DOCID: <WO___0149245A2_I_>

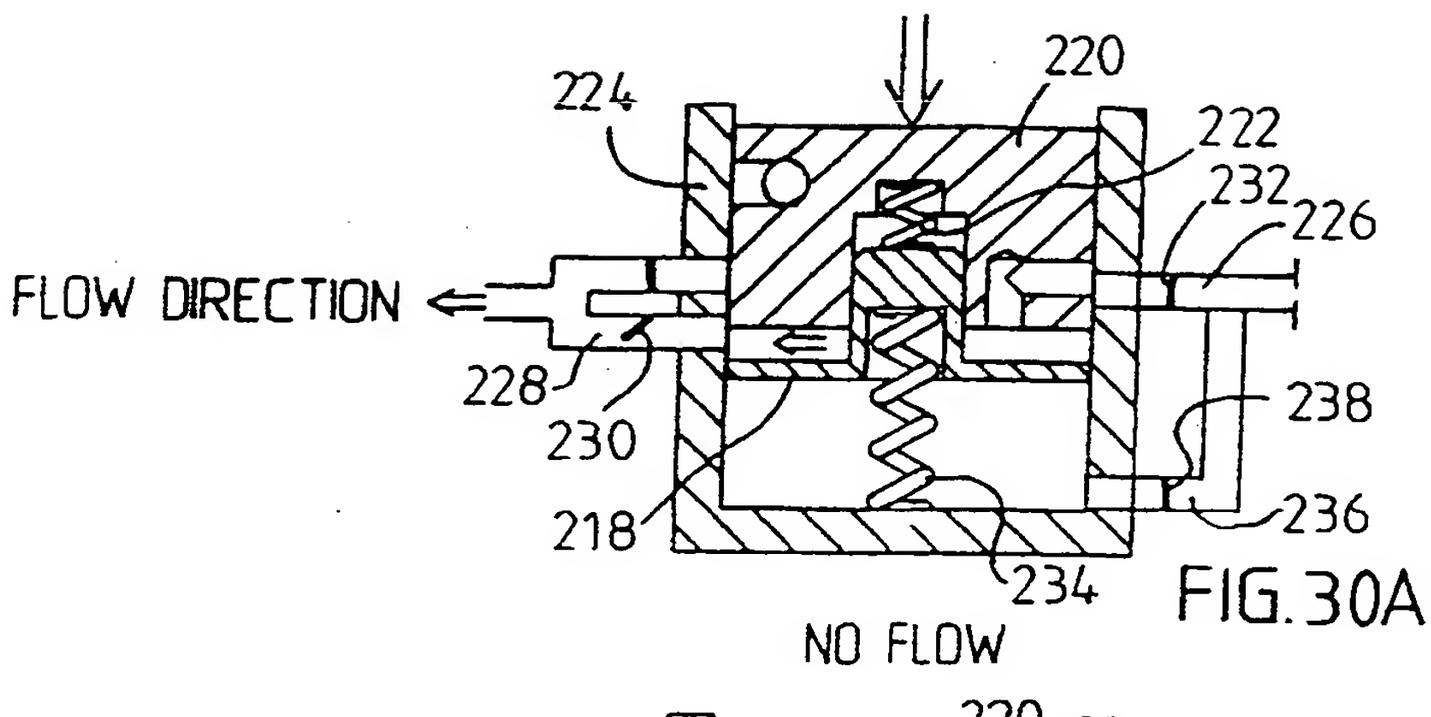


FIG.30A

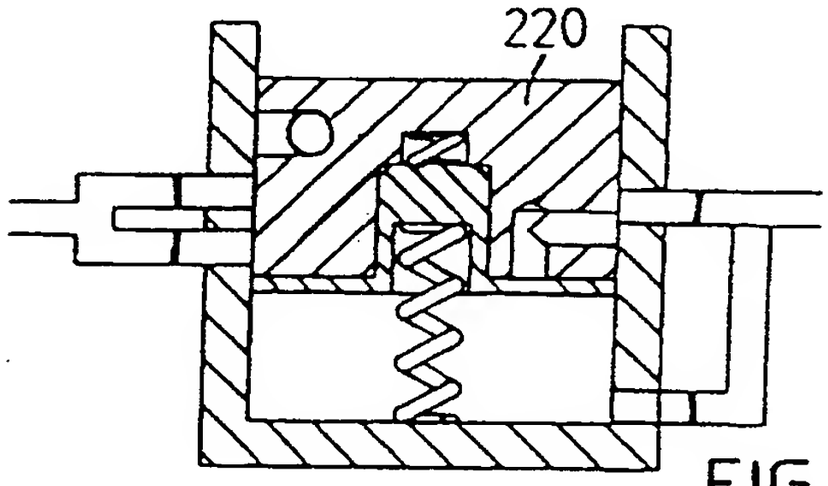


FIG.30B

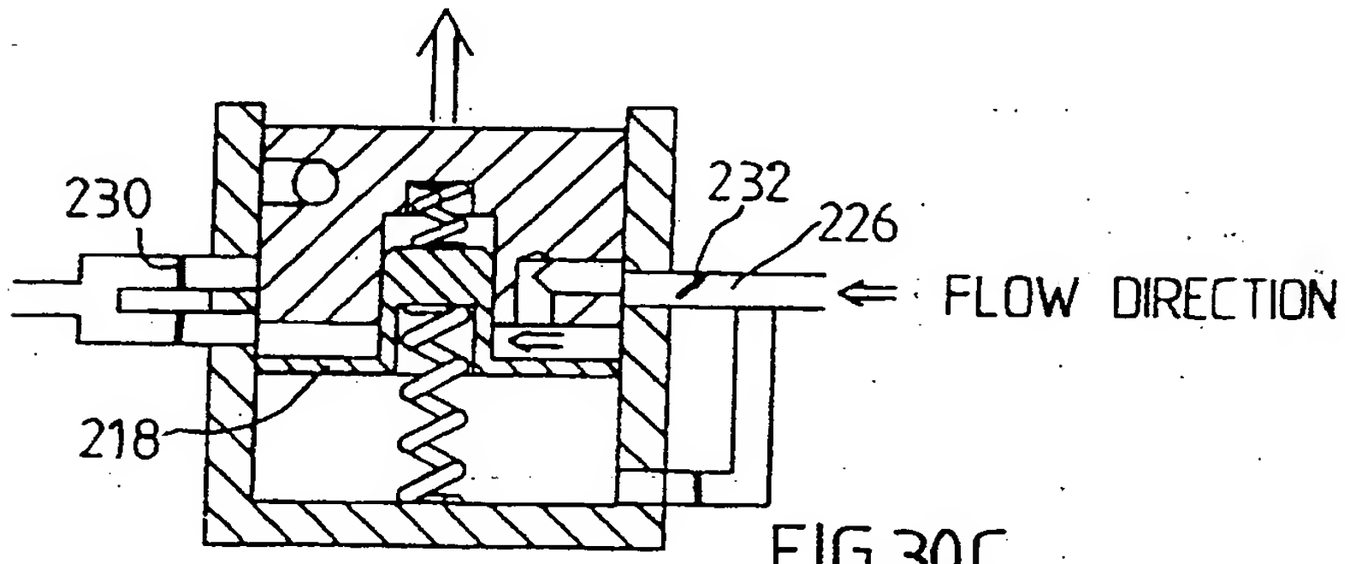


FIG.30C

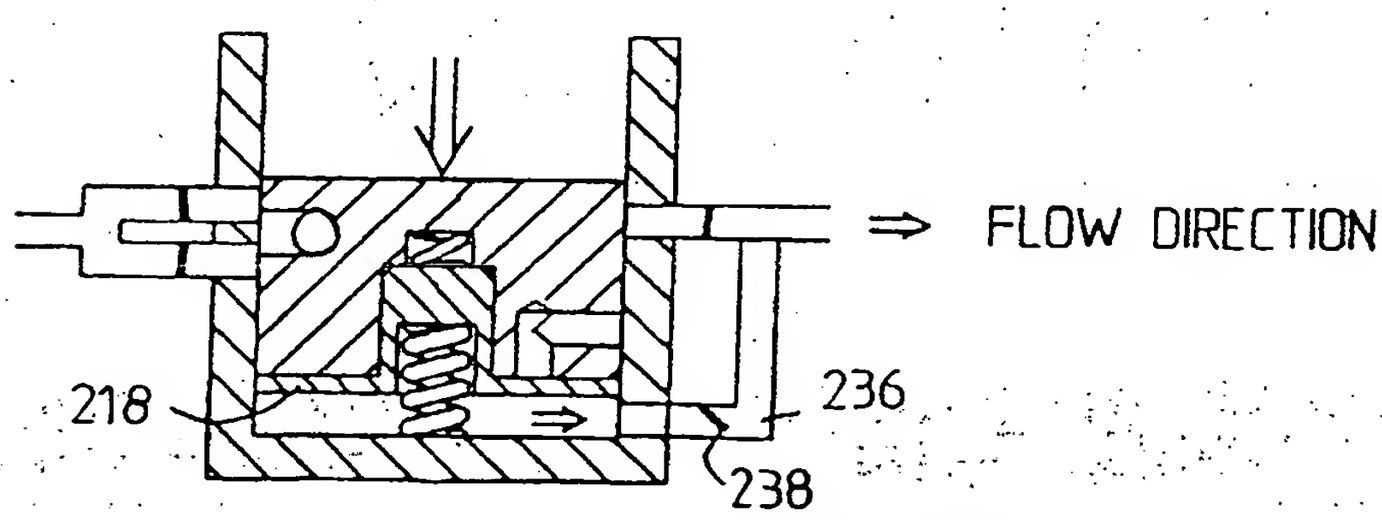


FIG.30D

SDOCID: <WO___0149245A2_I_>

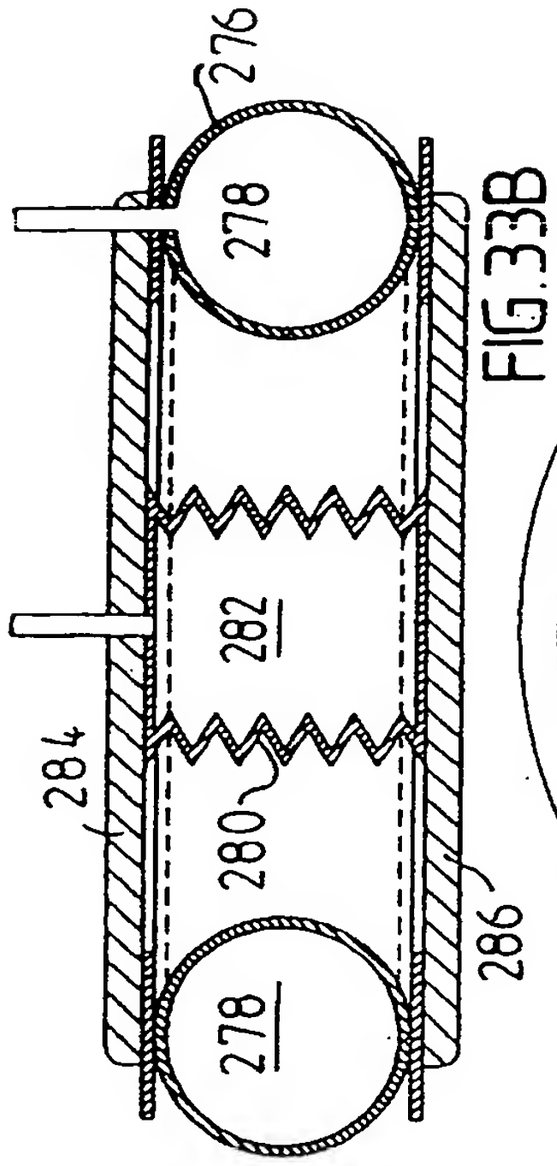


FIG.33B

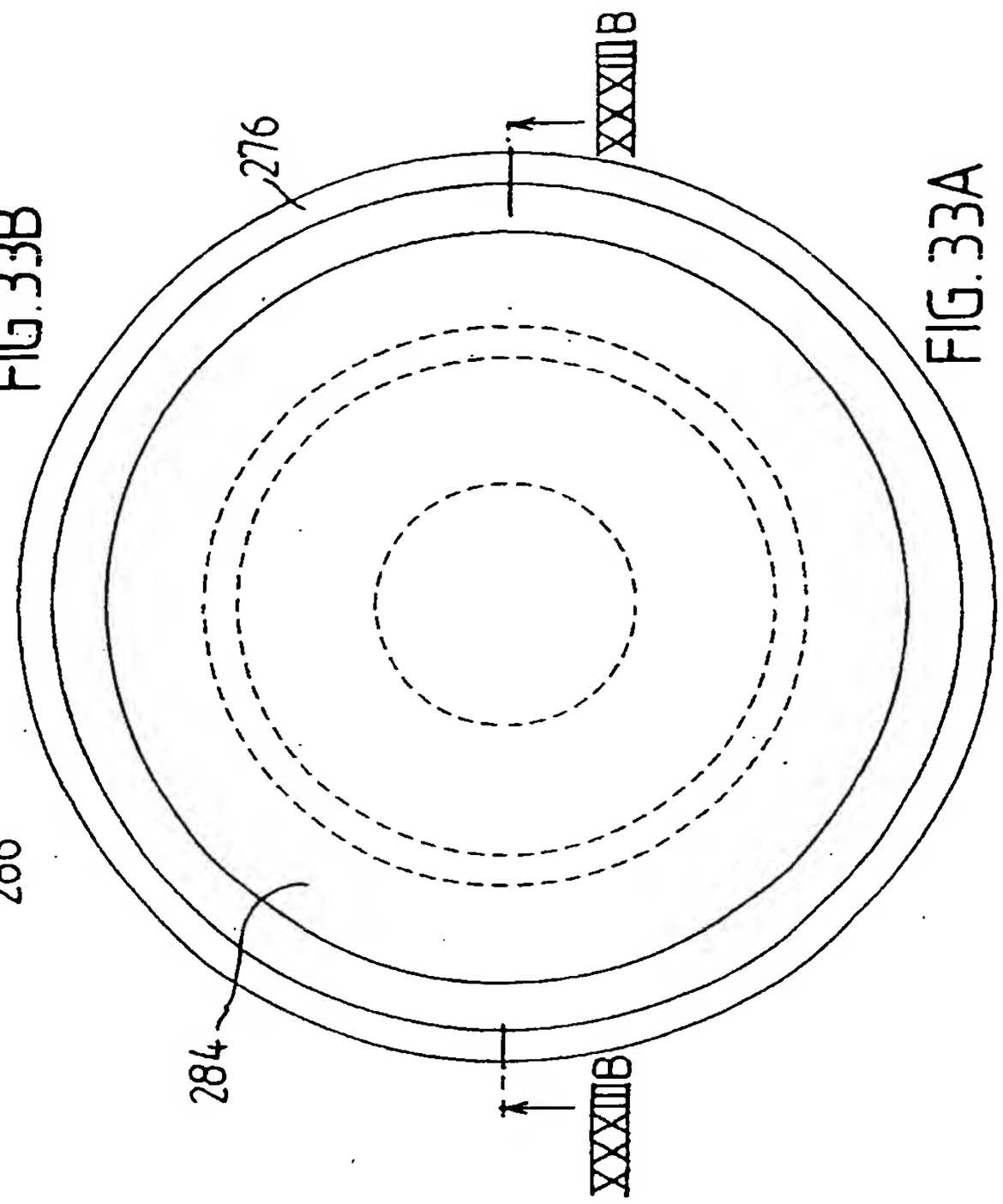


FIG.33A

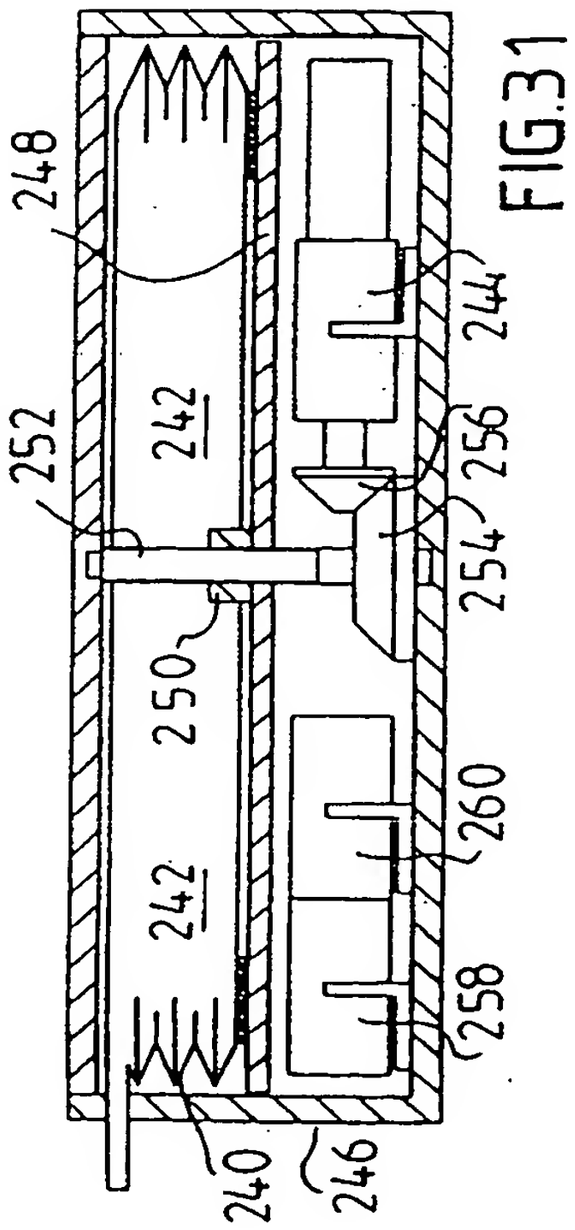


FIG.31

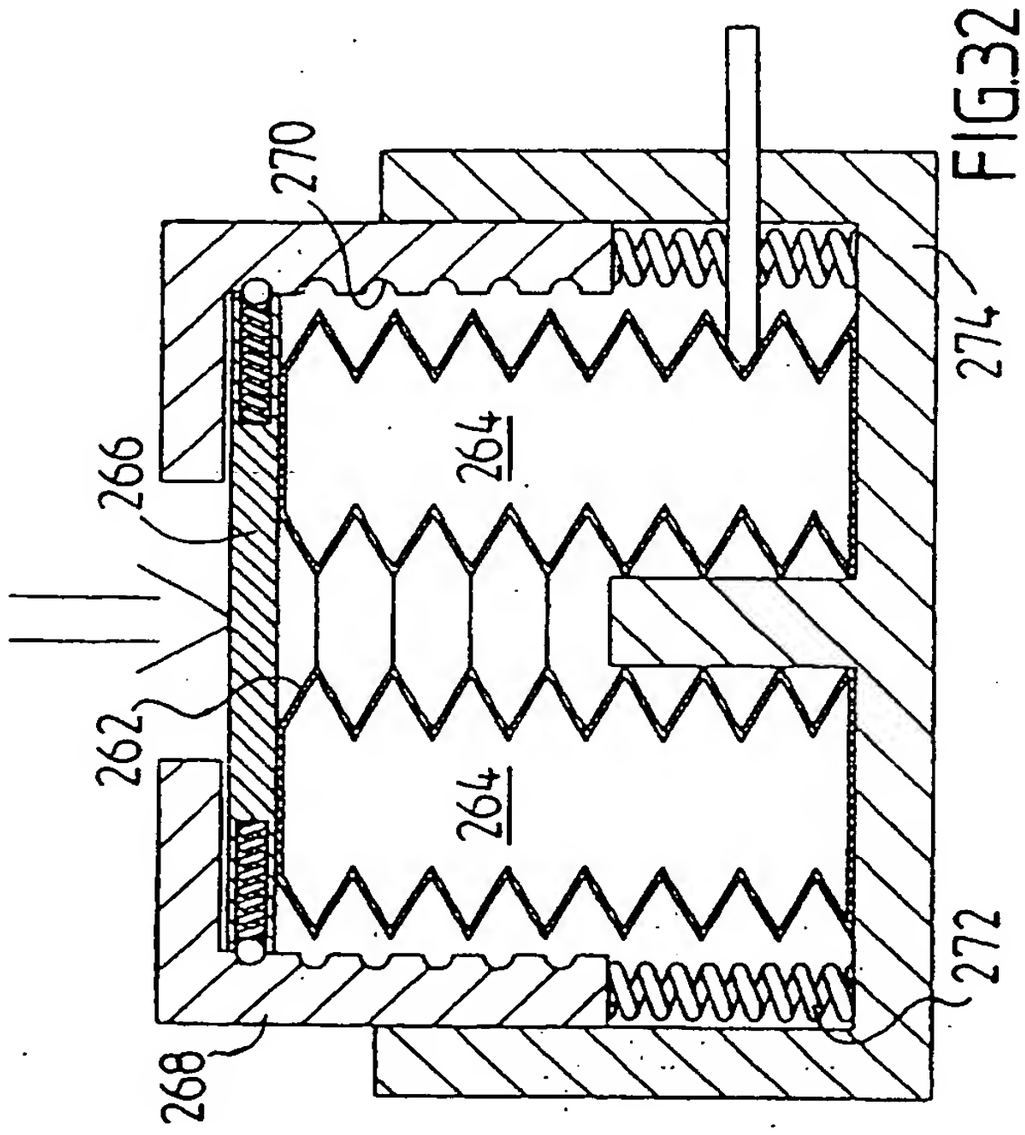


FIG.32

SDOCID: <WO___0149245A2_I_>

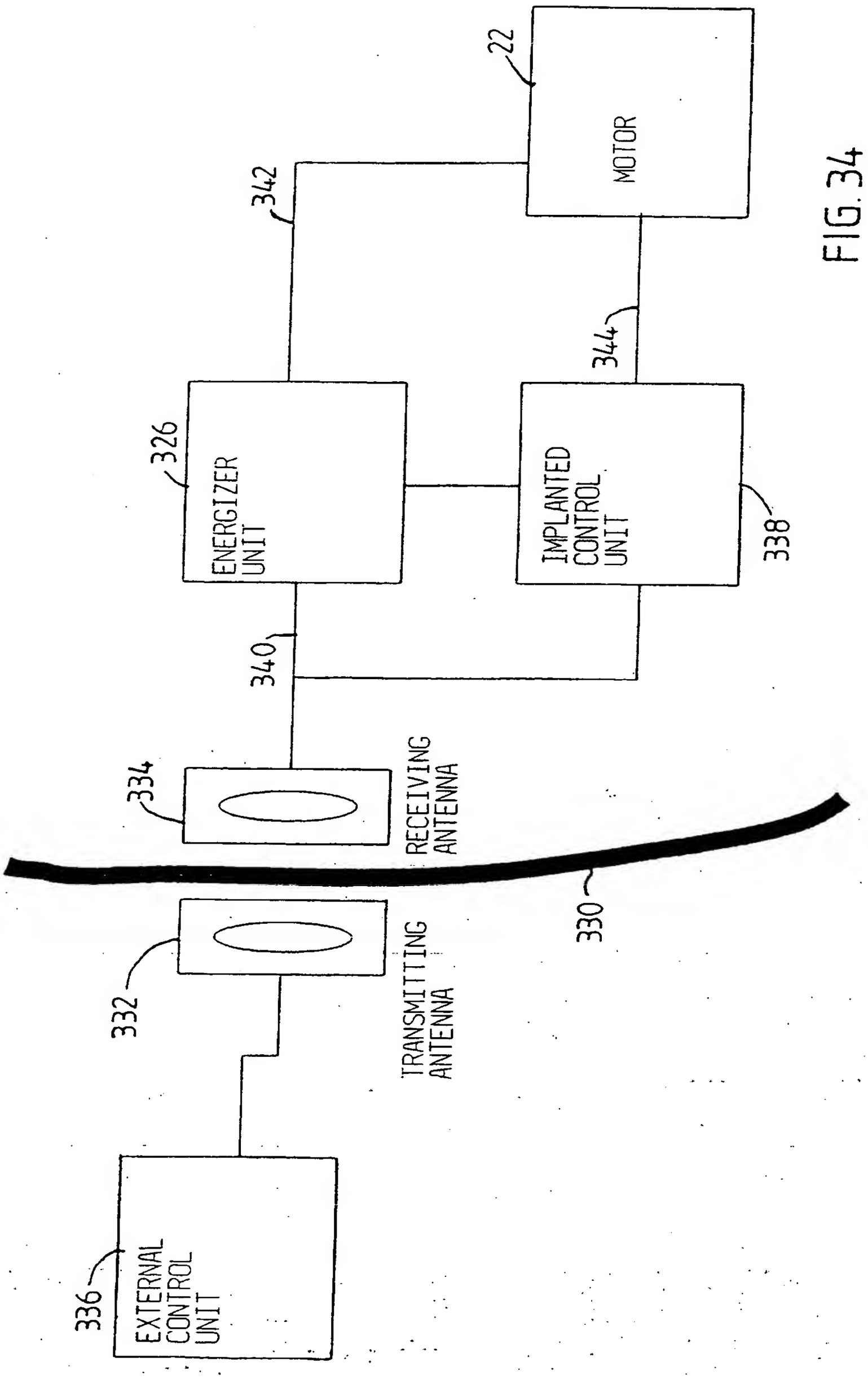


FIG. 34

SDOCID: <WO___0149245A2_I_>

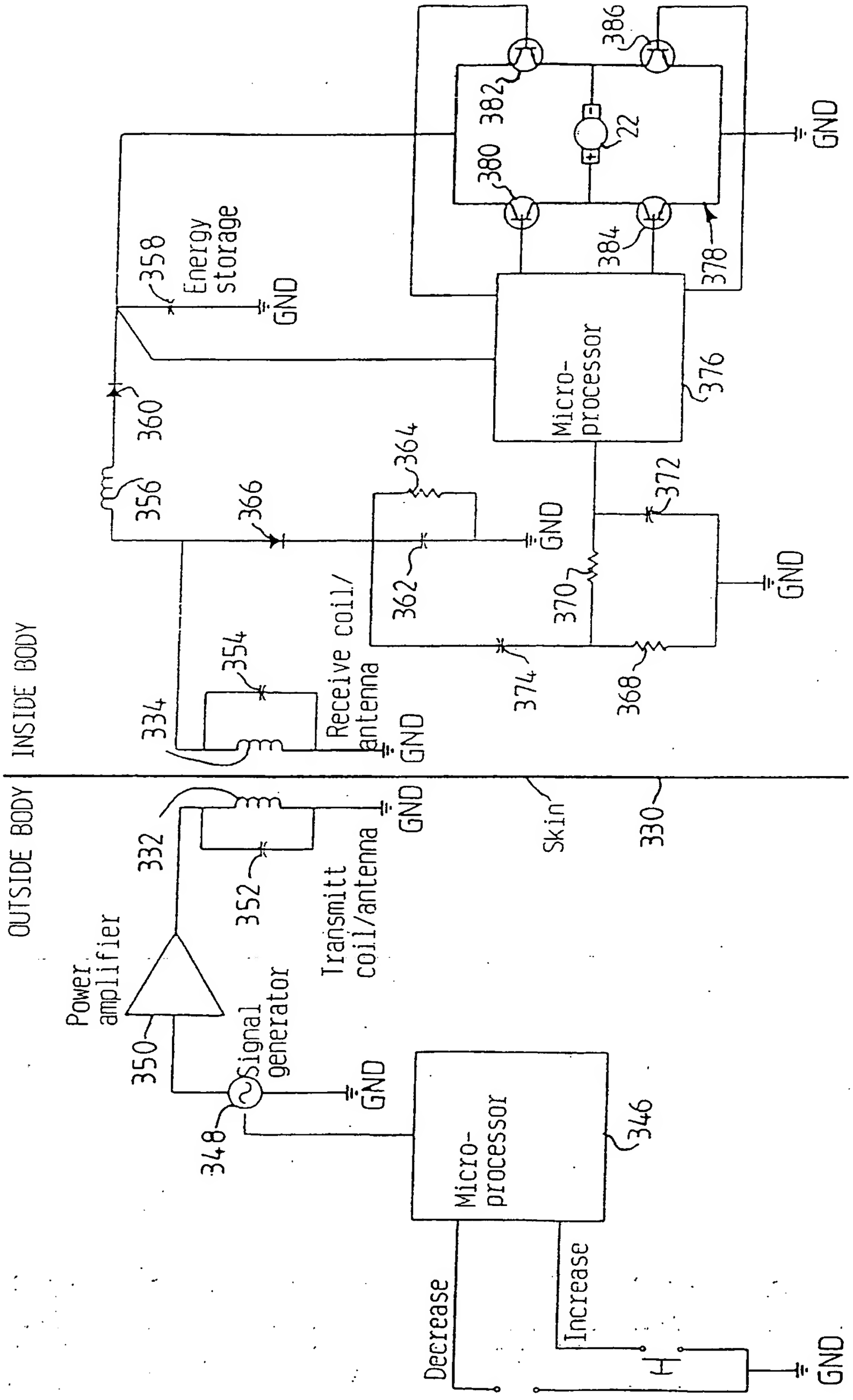


FIG. 35

DOCID: <WO___0149245A2_I_>

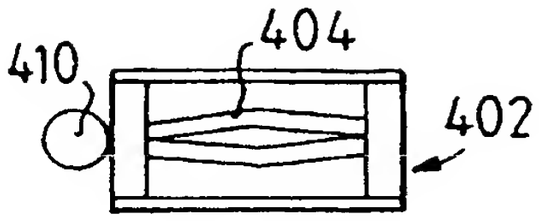


FIG.36A

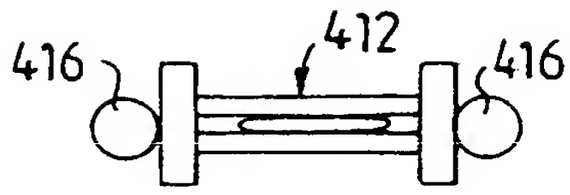


FIG.37A

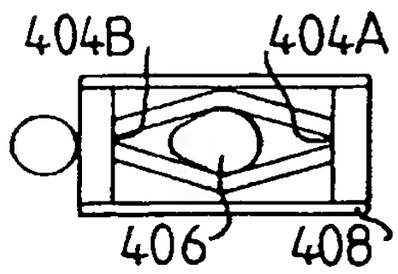


FIG.36B

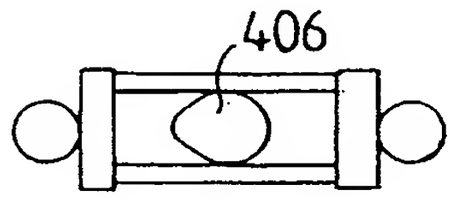


FIG.37B

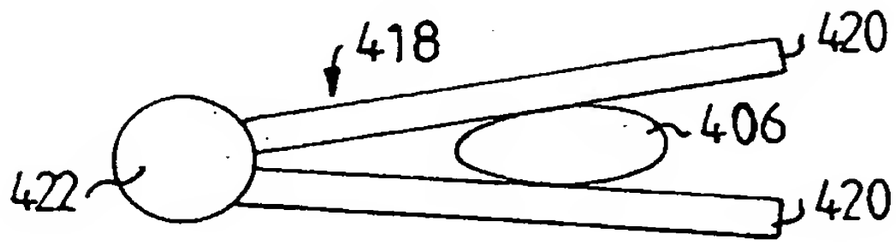


FIG. 38

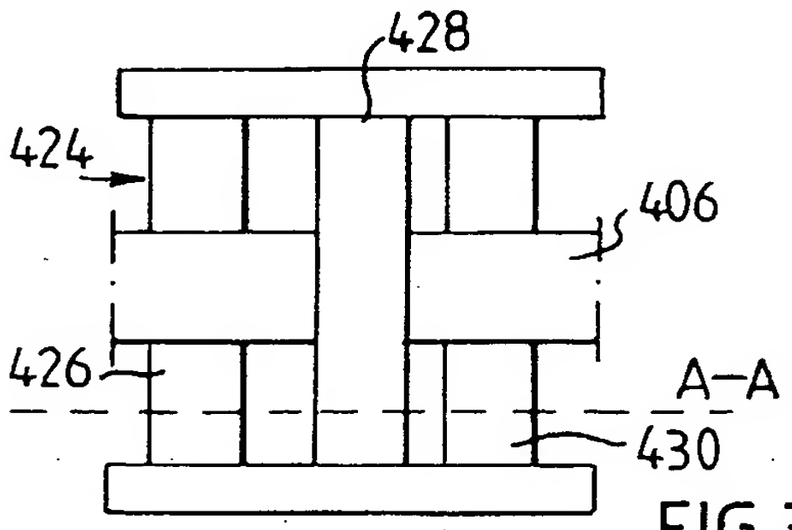


FIG.39A

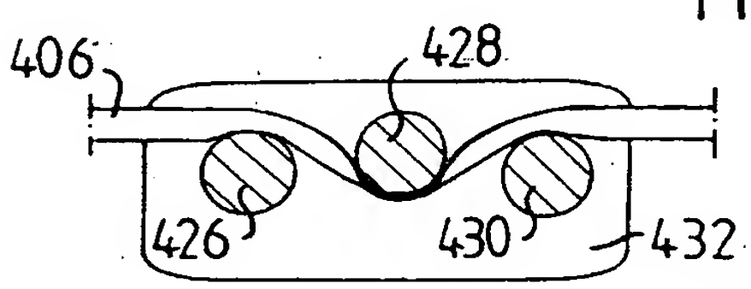


FIG.39B

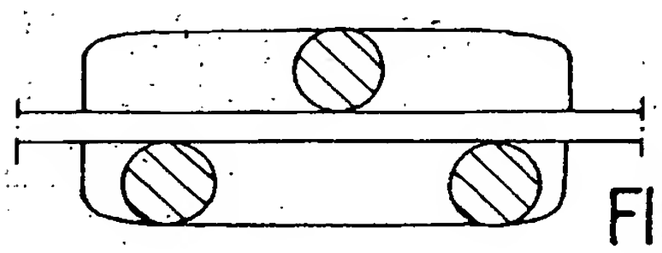


FIG.39C

ISDOCID: <WO___0149245A2_I_>

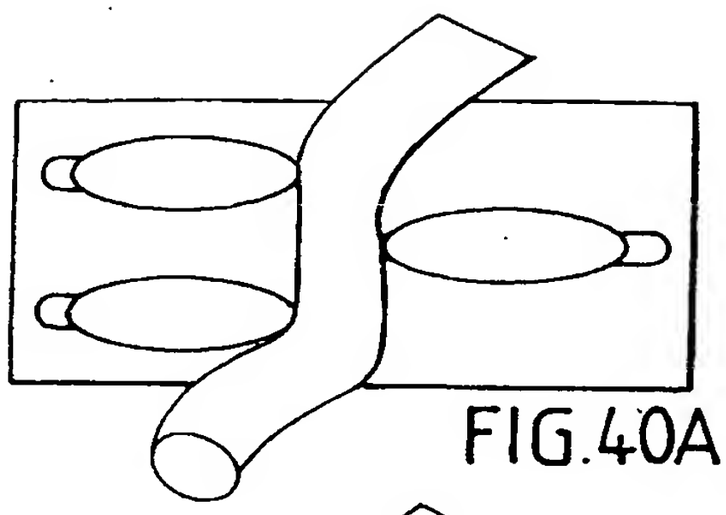


FIG.40A

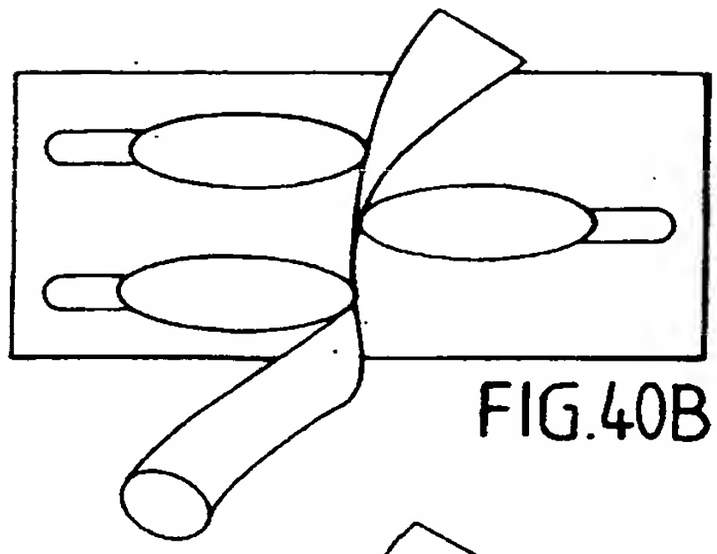


FIG.40B

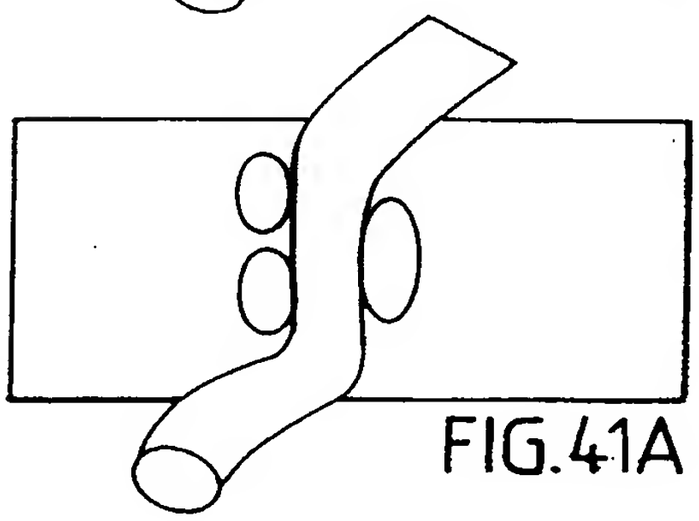


FIG.41A

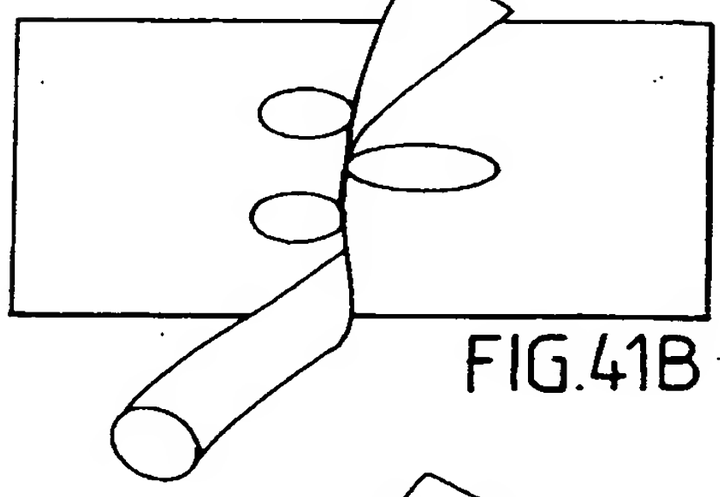


FIG.41B

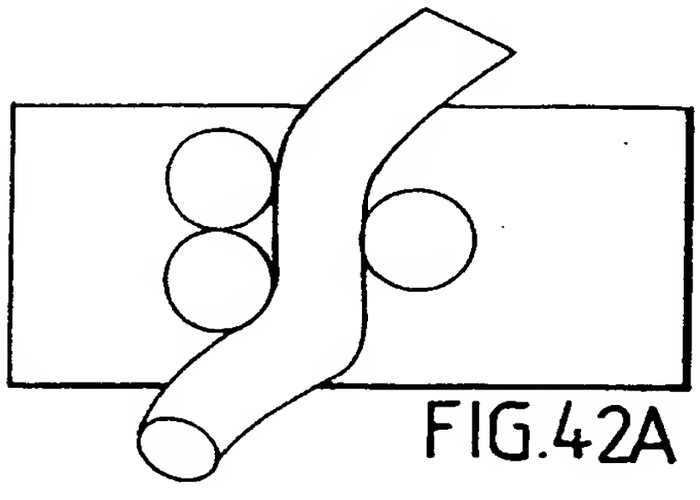


FIG.42A

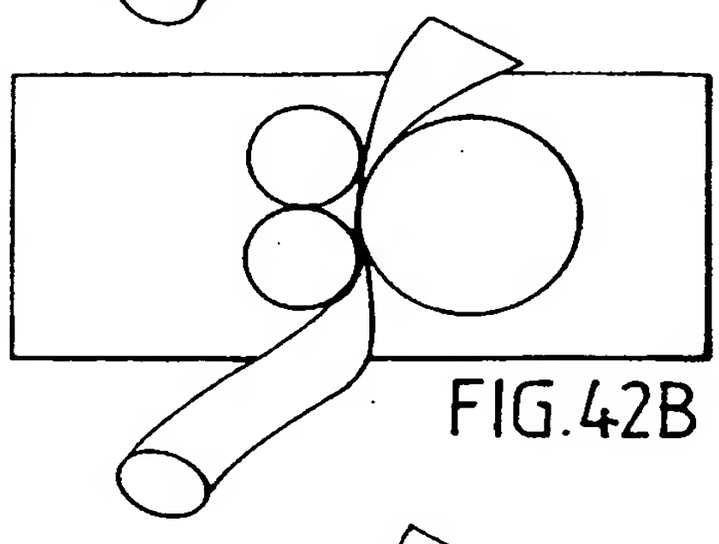


FIG.42B

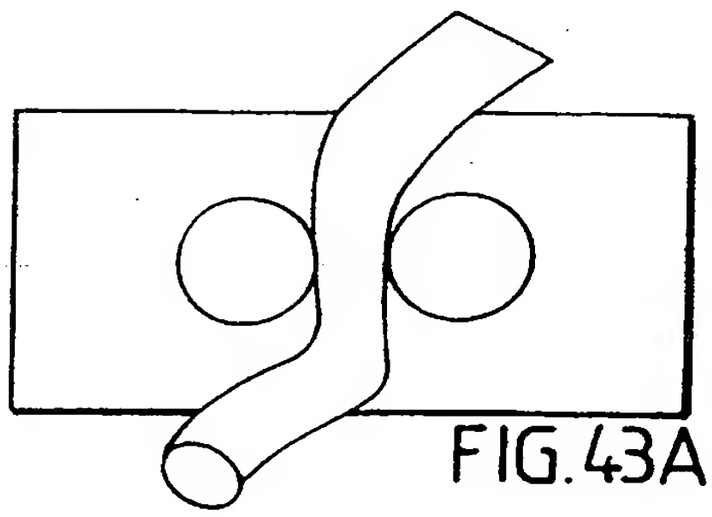


FIG.43A

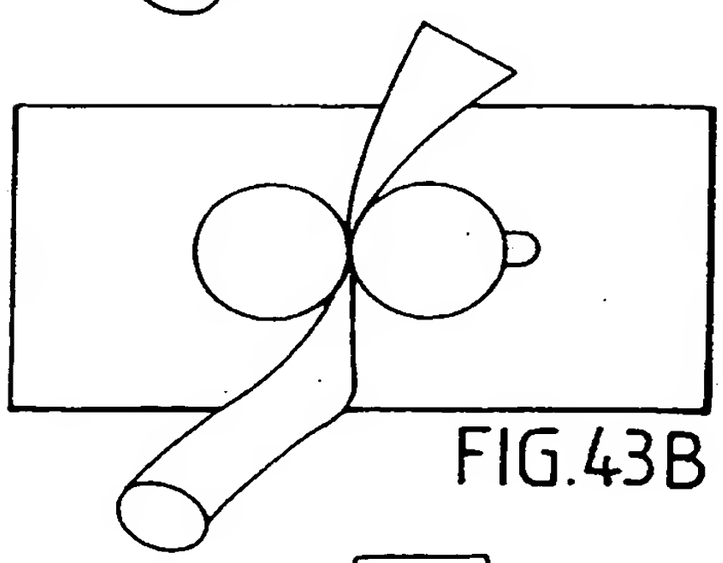


FIG.43B

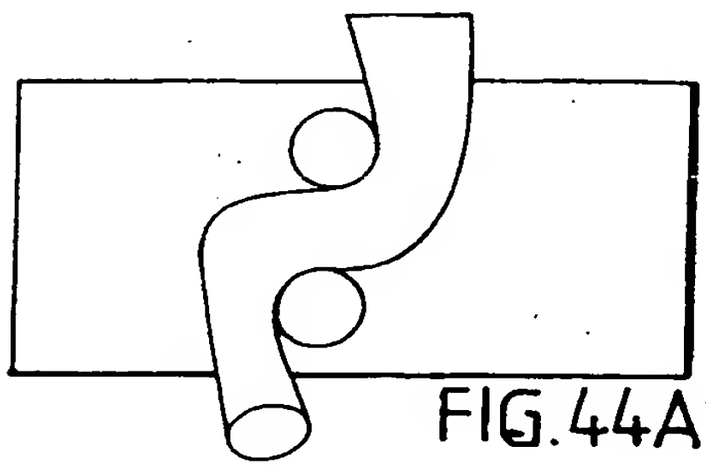


FIG.44A

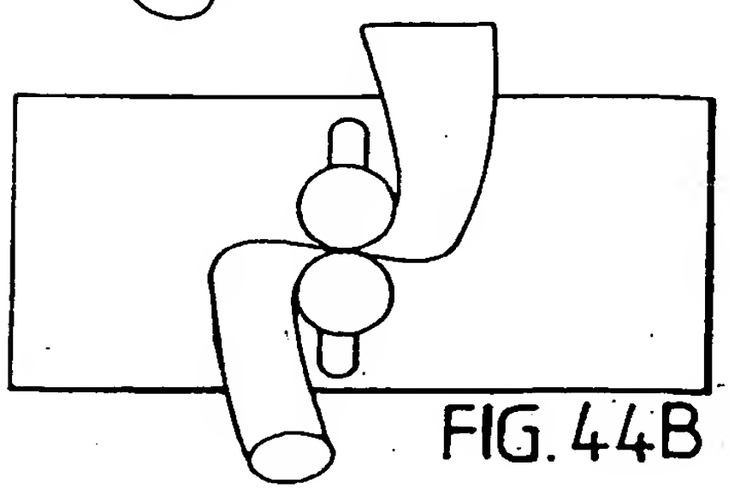


FIG.44B

;DOCID: <WO___0149245A2_I_>

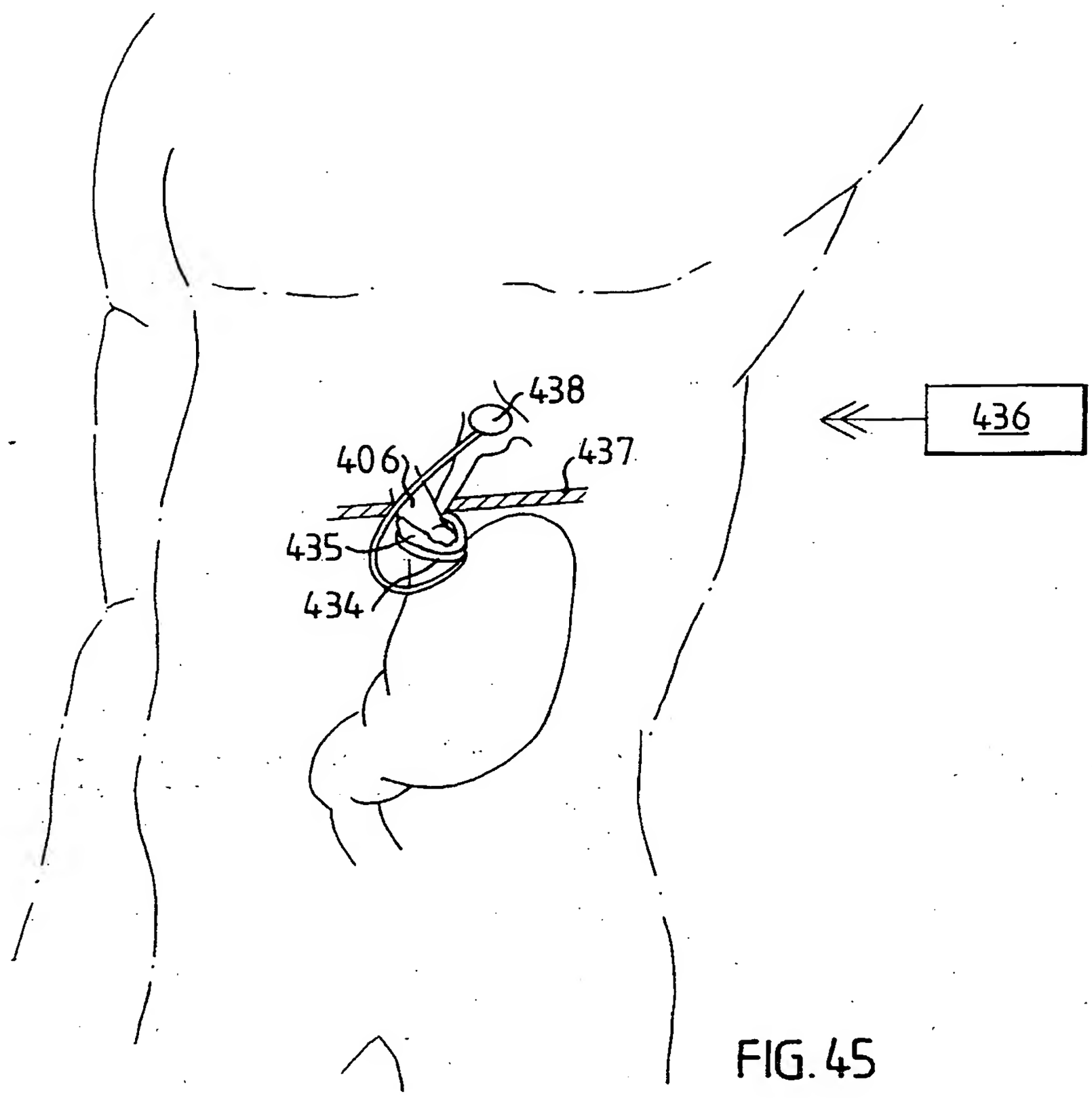


FIG. 45

SDOCID: <WO___0149245A2_I_>

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
12 July 2001 (12.07.2001)

PCT

(10) International Publication Number
WO 01/49245 A3

(51) International Patent Classification[7]: A61F 5/00 // A61B 17/12

(21) International Application Number: PCT/SE01/00228

(22) International Filing Date: 7 February 2001 (07.02.2001)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
09/502.074 10 February 2000 (10.02.2000) US

(71) Applicant *(for all designated States except US)*: **IT-MEDICAL AG** [CH/CH]; Zugerstrasse 74, CH-6341 Baar (CH).

(72) Inventor; and

(75) Inventor/Applicant *(for US only)*: **FORSELL, Peter** [SE/CH]; Kirchgasse 4, CH-6313 Menzingen (CH).

(74) Agents: **HAGSTRÖM, Leif** et al.; Bergenstråhle & Lindvall AB, P.O. Box 17704, S-118 93 Stockholm (SE).

(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.

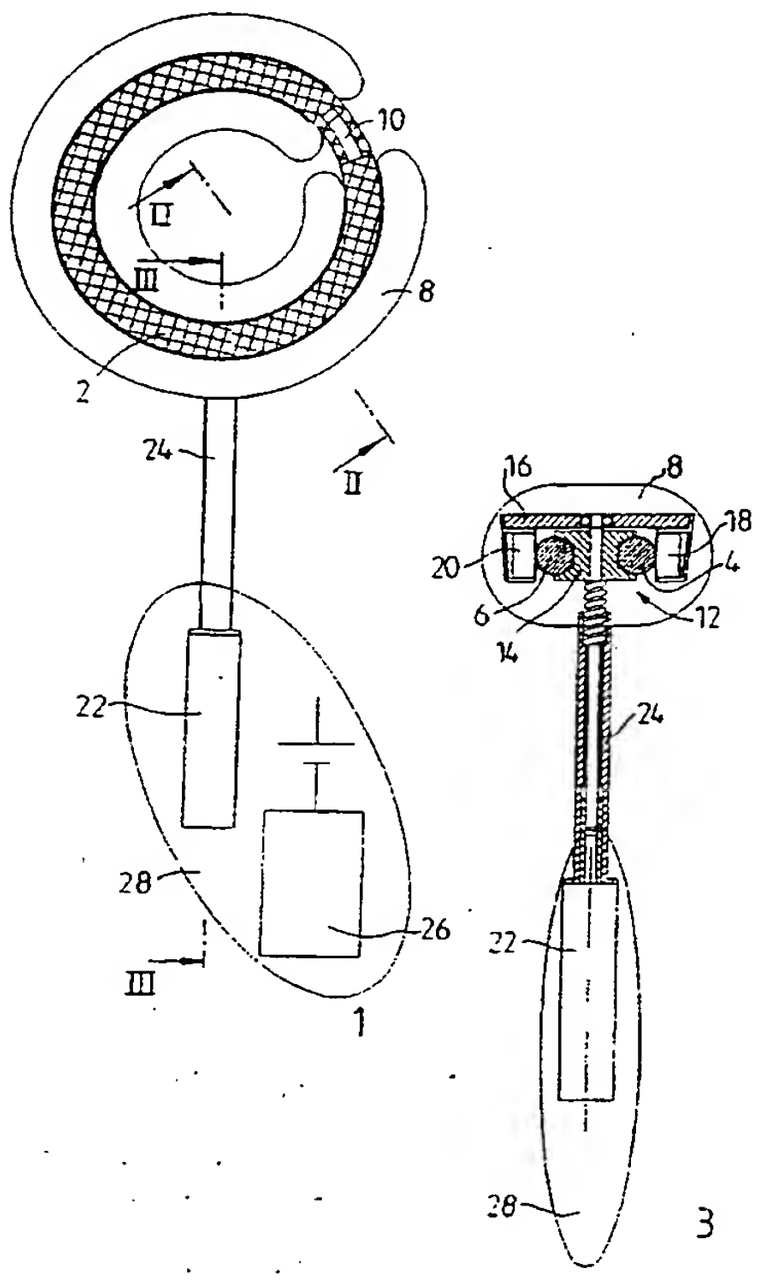
(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published:
— *with international search report*

[Continued on next page]

(54) Title: MECHANICAL HEARTBURN AND REFLUX DISEASE TREATMENT APPARATUS

(57) Abstract: A heartburn and reflux disease treatment apparatus for surgical application in the abdomen of a patient comprises an adjustable restriction device (2) adapted to engage the stomach close to the cardia or esophagus to form a restricted food passageway in the stomach or esophagus of the patient. A post-operation adjustment device (12) is designed to mechanically adjust the restriction device, preferably in a non-invasive manner, to enlarge or restrict the food passageway. The treatment apparatus allows post-operation daily adjustments of the restriction device to enlarge the food passageway when the patient eats and to restrict or close the food passageway between meals.



WO 01/49245 A3

--- *upon request of the applicant, before the expiration of the time limit referred to in Article 21(2)(a)*

(88) Date of publication of the international search report:
24 January 2002

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

ISDOCID: <WO___0149245A3_I_>

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 01/00228

A. CLASSIFICATION OF SUBJECT MATTER

IPC7: A61F 5/00 // A61B 17/12
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC7: A61F, A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and. where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5938669 A (KLAIBER ET AL), 17 August 1999 (17.08.99), figure 1, abstract	1-10,34-36, 44-107, 109-119
A		11-33,37-43, 108,120
	--	
X	US 5771903 A (JAKOBSSON), 30 June 1998 (30.06.98), figure 1, abstract	1
	--	
A	US 4271827 A (ANGELCHIK), 9 June 1981 (09.06.81), abstract	1-120
	--	

[X] Further documents are listed in the continuation of Box C. [X] See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
6 June 2001	19 -06- 2001
Name and mailing address of the ISA Swedish Patent Office Box 5055, S-102 42 STOCKHOLM Facsimile No. + 46 8 666 02 86	Authorized officer Ingrid Falk/EK Telephone No. + 46 8 782 25 00

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 01/00228

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P,X	WO 00/15158 A1 (SOFRADIM PRODUCTION), 23 March 2000 (23.03.00), figures 1-4, abstract ---	1-27,32,33, 44
P,X	WO 00/09047 A1 (FORSELL, PETER), 24 February 2000 (24.02.00), figures 1-35 ---	1-120
E,X	WO 01/12078 A1 (BLOMBERG, AXEL), 22 February 2001 (22.02.01), abstract --- ---	1

SDOCID: <WO___0149245A3_I_>

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE01/00228

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

.../...

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☒ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees.

SDOCID: <WO___0149245A3_I_>

According to rule 13.2, an international application shall relate to one invention only or a group of inventions linked by one or more of the same or corresponding "special technical features", i.e. features that define a contribution which each of the inventions, considered as a whole, makes over the prior art.

Such a link between all the subject of claims 1-120 would be the post- operation adjustment device designed to mechanically adjust the restriction device. An invention comprising this feature is disclosed in the documents US 5771903 A or US 5938669 A. The documents reveal a restriction band that includes a post-operation adjustment device designed to mechanically (filling a cavity in the band with a liquid) adjust the band.

According the following inventions were found:

1. Claims 1-11, 34-36, 44-120 directed to a heartburn and reflux disease treatment apparatus comprising a post-operation adjustment device disigned to mechanically adjust a restriction device.

2. Claims 12-27, 32, 33 directed to a heartburn and reflux disease treatment apparatus, wherein the adjustment device is adapted to adjust the longitudinal extension of an elongated restriction device.

3. Claims 28-31 directed to a heartburn and reflux disease treatment apparatus, wherein the adjustment device is adapted to turn pivoted elements of a restriction device.

4. Claims 37 directed to heartburn and reflux disease treatment apparatus wherein the adjustment device is adapted to pull a first portion of a restriction member from a second of a restriction member opposite the first portion.

5. Claims 38-39 directed to a heartburn and reflux disease treatment apparatus wherein the adustment device is adapted to squeeze the stomach between two elements.

6. Claims 40-43 directed to a heartburn and reflux disease treatment apparatus wherein the adjustment device is adapted to bend a portion of the stomach or esophagus.

INTERNATIONAL SEARCH REPORT

Information on patent family members

28/05/01

International application No.
PCT/SE 01/00228

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5938669 A	17/08/99	EP 0876808 A	11/11/98
US 5771903 A	30/06/98	AT 192318 T	15/05/00
		DE 69516690 D,T	01/02/01
		EP 0769282 A,B	23/04/97
US 4271827 A	09/06/81	NONE	
WO 00/15158 A1	23/03/00	NONE	
WO 00/09047 A1	24/02/00	NONE	
WO 01/12078 A1	22/02/01	NONE	

DOCID: <WO___0149245A3_I_>